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# Editorial Board

The Editorial Board of Q Bulletin was established in 2019.



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# Content

# Q Bulletin Ministry of Health Malaysia

# INTRODUCTION

The Q Bulletin of the Ministry of Health Malaysia is a peer-reviewed journal addressing quality assurance/improvement study related to health care. The journal welcomes original contribution from representatives of all health professions from health-related backgrounds in the discipline of quality assurance/quality improvement.

*Your manuscript should include abstract (up to 300 words), main text (up to 4000 words; excluding abstracts, tables and figures) and maximum of 5 tables and/or figures.*

**1. Title**

**2. Author's Name & Affiliation**
Full name of authors and clearly indicated corresponding authors with contact email.

**3. Abstract**
Summarise your work, including a brief background to the problem, the method for your quality improvement project, overall results and conclusion. Please include 3-5 appropriate keywords.

**4. Problem**
Summarise the problem and focus of your project. Give some details about your local context. Include here the SMART aim of your project.

**5. Background**
Give background information about the problem and summarise the literature on existing evidence that this problem exists, factors contributing to the problem and strategies that has been done in the past.

**6. Measurement**
Describe measures that you have selected for studying processes and the outcomes of the intervention(s). Describe plan for data collection and include the results of your baseline measurement (verification study).

**7. Initial assessment of the problem**
Describe what processes are involved in your problem including the critical steps that in the processes that will contribute to the achievement of your final goal. Describe the perceived factors that could contribute to the problem and how you quantify them. Include here the results of the study that you conducted to identify the contributing factors to the problem.

**8. Strategy**
Explain your strategy for improvement to the reader and discuss how you implemented your improvement cycles. For each PDSA cycle you should describe your aim, your change hypothesis and strategy for change. Describe how you implemented the change and the data you collected. Describe your key learning from each cycle of change, and discuss how this learning impacted on your change process. How well did your predictions of what change was needed match your outcomes? What worked more effectively than anticipated and what had less effect than predicted?

**9. Results**
Provide a summary of what your results using appropriate chart or diagram. Compare your results to your baseline measurement.

**10. Lessons and limitations**
Discuss the lessons, the strengths and limitations of the project. If you were to undertake this project again, what would you do differently?

**11. Conclusion and the next steps**
Reflect on your aims statement – did your project achieve its aims? Did you adjust your aims as you went along? Was it a useful project? Were your measures appropriate and did you use balancing measures?

**12. References**
Use the Vancouver style for referencing.

**13. Acknowledgements**
Please include here the names of anyone who is not on the author list but whose input you wish to acknowledge.

**14. Communication**
Full version of the guideline can be found at the last section of this journal. For submission purpose, please contact ihsrqa@moh.gov.my

# EDITORIAL

## Our Q Bulletin is Now Available Online!

Dear Readers,

In the first edition of this Q Bulletin late last year, I shared with you our hope that one day Q Bulletin will adopt a more efficient publication process. Alhamdulillah, the dream came true this year when Mrs Khalidah Maruan, one of the editorial members attended a one-day coaching workshop on Malaysian Journal Management System (MyJMS) Services organised by the Ministry of Higher Education. The workshop had guided us on the process needed to develop a platform for online journal publishing from setting a journal website to publication of a journal issue.

MyJMS is a web-based manuscript submission and peer-review system for scholarly journals and conference proceedings and serves as an initiative to improve the quality and standard of journal publishing, saves time and costs for journal management process and encourage online publishing of journals and thus increase global access.

We strongly believe that this online system will help Q Bulletin's editorial team to improve record keeping and efficiency of editorial process as everything is in one place, therefore increase submission turn-around speed. Additionally, our authors, editors' team and reviewers will be able to track the progress of the manuscripts through the system.

Online version of Q Bulletin publishing process involved establishing the journal website, creating issue for the manuscripts to be published upon, editorial steps which include submission, peer-review, copyediting and production and lastly application of electronic journal serial number (e-ISSN).

Finally, the efforts were fruitful when we successfully made the hardcopy of Jan-Dec 2019 Q Bulletin went online! The issue was officially available on the web on 19 Mac 2020. **HEARTY CONGRATULATIONS** to the team! Indeed, this achievement has marked another significant milestone in the roadmap of the Quality Assurance/Improvement programme in the MOH.

Now you can browse all Q Bulletin issue(s) and submit your manuscript at http://myjms.moe.gov.my/index.php/qbulletin/index

With the first manuscript submission received via the platform on 6 July 2020, we are extremely excited to explore and fully utilise the system. Lastly, we sincerely hope that our Q Bulletin will reach a wider target audience through this online platform, thereby facilitating dissemination and sharing of the best practices.

Dr Samsiah Awang

Editor-in-Chief

# REDUCING PAINFUL EXPERIENCES IN NEONATES DURING ROUTINE MINOR PROCEDURES IN SPECIAL CARE NURSERY: A QUALITY IMPROVEMENT PROJECT

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## Abstract

Neonates in Special Care Nursery (SCN) are constantly exposed to routine procedures that are painful. Repetitive painful exposures in neonates are known to have long-term deleterious effects that may surpass adulthood. A quality improvement project was designed to reduce the pain experienced by neonates during routine minor procedures in SCN unit of Hospital Tuanku Fauziah (HTF), a tertiary state hospital in Perlis, Malaysia. The Neonatal Infant Pain Scale (NIPS) was used as a pain assessment tool in neonates throughout the study. Several factors contributing to neonatal painful experience during routine procedures were identified, including poor awareness on neonatal pain perception, poor procedural etiquette among paediatric house officers, and lack of non-pharmacological pain relief used during the procedures. Interventional measures included adjunctive use of non-nutritive sucking via orthodontic Avent® pacifier, use of adjustable swaddling blanket via SwaddleMe® size S, and introduction of a clinical training module for the house officers. There were 159 neonates recruited in the pre-intervention period and 163 neonates evaluated in the post-intervention period. Our study revealed a significant decrease in neonatal painful experience during routine procedures, from 49.7% to 17.8% ($p<0.001$), exceeding the standard set at 20%. This comprehensive strategy of multimodal interventional measures effectively reduced pain perception in neonates during routine minor procedures in SCN, fostering the development of a local procedural guideline to ensure continuous good healthcare services in neonates.

**KEYWORDS:** Paediatrics, neonates, pain, quality improvement, patient-centred care.

## Problem

Neonatal hospital care is divided into Neonatal Intensive Care Units (NICUs) and Special Care Nurseries (SCNs), based on the level of care and medical attention required. Most NICUs worldwide practise procedural guidelines to prevent or minimise pain, particularly during invasive procedures, such as endotracheal intubation, endotracheal suctioning and ocular examination (1). However, little attention is given to the more stable neonates who are subjected to painful routine minor procedures in SCN. Routine minor clinical procedures that cause pain in neonates include venepuncture, intravenous cannulation, heel prick, intramuscular vaccination, orogastric tube insertion and tape removal (2,3).

Hospital Tuanku Fauziah (HTF), Kangar, Perlis, Malaysia is a tertiary state hospital with major clinical specialties catering to a population of 260,000 people. Its SCN unit has a high turn-over frequency with its bed occupancy rate (BOR) reaching up to 140% in the year 2016. Our SCN unit is managed by a paediatrician in-charge, assisted by a dedicated ward sister. The managing clinical team comprises of between 15 to 20 health personnel at any particular time. A majority of the routine minor procedures in SCN including venepuncture and intravenous cannulation are commonly performed by the paediatric house officers, whereas the less common procedures such as orogastric tube insertion are performed by nurses.

A preliminary study conducted from November until December 2016 revealed that 49.7% of neonates in SCN HTF experienced pain during routine minor procedures. This highly prevalent problem became the focus of our study which aimed to reduce painful neonatal experience during routine minor procedures to less than 20% within a year. It is important to note that prior to this, there were no specific pain management guidelines for in-ward neonates in SCN, HTF. Routine monitoring or assessment of pain in neonates during the conduct of routine minor procedures was also not performed.

## Background

The pain experienced by neonates during routine clinical procedure is a universal concern. This is evident in a published systematic review on the epidemiology of pain in neonates, which found that pharmacological and non-pharmacological interventions were rarely implemented to reduce pain in neonates prior to procedural conduct (4).

Improving pain management in neonates is not only an ethical expectation from parents, but also prevents future adverse outcomes caused by the repetitive painful stimuli. These include altered pain sensitivity, emotional and behavioral changes, and future learning disabilities (5) that may last into adulthood. Regardless of the duration of exposure in neonates, each repetitive painful exposure has a cumulative effect hence creates substantial developmental consequences including effects on their physiological maturity, brain microstructure and networks, as well as disturbances to their hypothalamic-pituitary-adrenal axis (5).

A number of procedural guidelines for pain relief in neonates during clinical procedures were developed to fit local and regional practices (1,6,7). A cross sectional study in 2008 found a modest increase in measures to prevent neonatal pain in the United Kingdom since a survey in 2000, but there was no pain guideline in nearly 25% of the neonatal units and no guidelines for routine painful procedures in the majority of neonatal hospital care (7). Lack of enforcement also rendered the guideline ineffective, as observed in a study involving eight Australian states and territories which found that only 39% of neonatal units implemented a procedural guideline to control pain in neonates during routine procedures (8).

Previous studies identified various factors proven to cause pain in neonates. At the same time, various effective methods of pain relief have been introduced and were clinically proven to provide comfort during procedural conduct, however, they are often underused (9,10). These include non-pharmacological relief and pharmacological interventions.

Lack of physical comfort during painful clinical procedures has been proven to cause pain in neonates during these events (11). Effective use of non-pharmacological methods including non-nutritive sucking, proper swaddling technique and facilitated tuck (11,12), and direct breastfeeding during procedural conduct (13) have been demonstrated to relieve pain in neonates.

Environmental noise has also been associated with negative developmental outcomes and stress in hospitalised infants (14). Hence a conducive environment (15) such as adequate lighting, good room ventilation and minimal ambient noise (16) has been shown to reduce pain perception in neonates during procedures.

Furthermore, lack of formal clinical training for paediatric interns who are the front-liners in the clinical field may contribute to clinical incompetency and lack of confidence in performing clinical procedures (17,18). This leads to a low procedure success rate, resulting in repetitive procedures.

It is also important to note that pharmacological pain relief in neonates has a definitive role during invasive procedures. A good example is oral sucrose 24% which is listed as a 'Grade A' recommendation for pain-relief in neonates during blood-taking by the Association of Paediatric Anaesthetist of Great Britain and Ireland (APA) (19). However, oral sucrose 24% is not listed in the Malaysia Book of Drug Formulary, hence is unavailable for use during routine procedures in most public hospitals.

## Measurement

The general objective of this study was to reduce the percentage of neonatal painful experience during routine minor procedures in SCN to less than 20% within a year. The specific objectives included the identification of the contributing factors to painful experience during minor procedures in neonates, the implementation of improvement strategies, and subsequent evaluation of strategies' effectiveness. This study was conducted from November 2016 until November 2017.

Pain was the main parameter of our study assessment. We used the Neonatal Infant Pain Scale (NIPS) score, a multi-dimensional tool validated for use in neonates (20). NIPS is a composite measure that includes both physiological and behavioural cues, whereby a score of more than three (from a total score of 10) signifies pain (20). Thus, a reduction in the number of cases of NIPS score of more than three, constitutes an improvement.

Based on local consensus, a standard of less than 20% of neonates with painful experience during routine minor procedure in SCN HTF was set.

$$\textit{Percentage of neonates experiencing pain during minor procedures} = \frac{\textit{Number of neonates with NIPS} > 3}{\textit{Number of neonates subjected to routine minor procedures)}} \times 100\%$$

NIPS scoring was done during the routine minor procedures in SCN neonates, charted by independent house officers not primarily involved in the conduct of the procedure. Training programme on the use of NIPS and inter-rater consistencies among the house officers involved were assessed prior to the start of the study. The routine minor procedures included in the study were venepuncture, intravenous cannulation, orogastric tube insertion and tape removal.

Neonates from the Special Care Nursery (SCN) ward who were stable (i.e. neonates not needing supplementary oxygen therapy and not being treated for clinical sepsis), had gestational age of more than 37 completed weeks, had birth weight of 2,500 grams or more, were more than 24 hours of life and less than seven-day old and had good Apgar scores (defined as Apgar score of more than 7 at 1 minute and/ or more than 8 at 5 minutes) were included in this study.

Neonates with possible altered pain sensitivity were excluded from this study, including (i) neonates who were given analgesia or sedation within five days of study entry, (ii) neonates with neurological symptoms (i.e. restlessness, seizure), (iii)

syndromic babies, (iv) neonates with three or more prick marks at study entry, and (v) neonates with failed second procedural attempt of venepuncture, intravenous cannulation or orogastric tube insertion.

During the two-month verification study phase (Phase I: November to December 2016), data on the prevalence of pain in neonates during minor procedures and its contributing factors were collected. These included information regarding the provision of non-pharmacological pain relief during procedural conduct, ability of paediatric interns to demonstrate proper swaddling technique using the conventional swaddling blanket, interns' procedural etiquette, their theoretical performance in objective assessment of good pain management, and their knowledge on procedural conduct in neonates during routine minor procedures. These parameters were re-evaluated during Phase II from April to May 2017 to appraise the effectiveness of the interventional strategies.

The analyses were performed using IBM Statistical Package for Social Sciences (SPSS) version 20.0 for Windows. Descriptive statistics were used for selected variables. The results were presented as frequencies and percentage for categorical data while Pearson chi-square test of independence was used to study significant differences between pre-intervention and post-intervention in each study category.

## Initial Assessment of the Problem

The process of care related to the conduct of routine minor procedures in SCN neonates was outlined in Figure 1, and the critical steps that may aid in reducing the percentage of neonatal painful experience during routine minor procedures were marked with double asterisks (**).

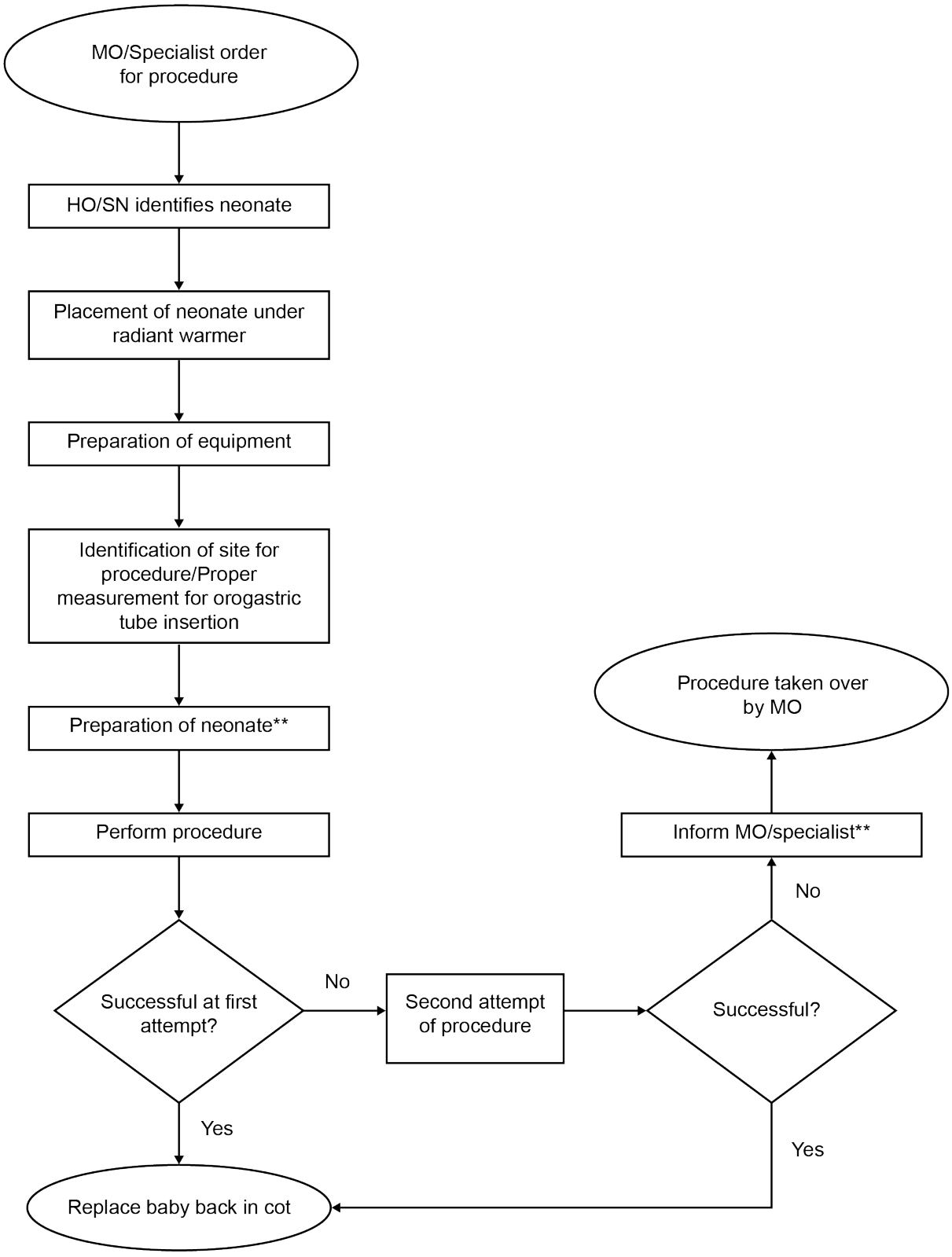
In the verification study, we assessed 159 neonates during routine minor procedures. We found that venepuncture was the most commonly performed routine minor procedures (n=102, 64.2%) in SCN, followed by intravenous cannulation (n=25, 15.7%), tape removal (n=29, 18.2%) and orogastric tube insertion (n=3, 1.9%). We found that up to 49.7% (n=79) of the neonates experienced pain during the conduct of routine minor procedures, predominantly contributed by venepuncture (n=56, 70.9%) followed by intravenous cannulation (n=15, 19.0%). Further analysis found that approximately 60% (n=91) of neonates in SCN, HTF were not given any form of pain relief during the conduct of routine minor procedures. At a more fundamental level, there was no standardised local or national guideline used for pain management in neonates during routine minor procedures in SCN, HTF. Prior to this quality improvement project, there was no formal training on this matter for paediatric interns prior to their rotation in neonatal wards.

A detailed analysis to delineate the contributing factors to neonatal painful experience during routine minor procedures showed that up to 80% (n=16) of paediatric interns in SCN rotation were unable to demonstrate correct swaddling technique using a conventional hospital swaddling blanket. Furthermore, during the basic theoretical assessment of good pain relief in neonates, 90% (n=18) of the paediatric interns failed to get the minimum required score. About 80% of the interns also did not use any form of non-pharmacological modalities to reduce pain during the procedures.

In a separate assessment among 80 neonates requiring venepuncture or intravenous cannulation, we found that 35% (n=28) of neonates were subjected to multiple pricks of three times and above without medical officer or specialist in-charge being informed.

## Strategy

Our intervention strategies were planned to address the issue of pain in neonates during routine clinical procedures including the preparation of neonates prior to procedural conduct which includes identifying the correct neonate for procedure, placing the neonate under pre-heated radiant warmer, preparation




*HO: House Officer* *MO: Medical Officer* *SN: Staff Nurse*
*** Critical Steps***

**Figure 1:** Flow-chart of process of care for the performance of routine minor procedures in SCN

of the equipment, and identifying the site for procedural conduct. This also included (i) enforcement of non-pharmacological pain relief usage during the conduct of routine minor procedures and (ii) training and privileging programme for the paediatric interns, which aimed to increase competency by providing formal hands-on workshop for the house officers prior to their SCN/NICU rotation.

Non-pharmacological pain relief during the conduct of routine minor procedures included adopting the use of non-nutritive sucking via an orthodontic Avent® pacifier and using a standardised swaddling technique via the SwaddleMe® blanket Size S. The insertion of orogastric tube precluded the use of pacifier. The use of pacifier was strictly during the routine procedures in SCN only, in accordance with our policy and status as a baby-friendly hospital since 1997.

The training and privileging programme for paediatric interns were constructed as a half-day hands-on workshop, made mandatory for all paediatric interns prior to their neonatal ward rotation. The workshop included a lecture session delivered by a dedicated paediatrician, aiming to create awareness on pain perception in neonates and the deleterious effects of long-term neonatal pain exposure. The lecture concluded with a theoretical examination consisting of 15 true or false questions evaluating the basic knowledge, clinical skills and knowledge on non-pharmacological pain relief in neonates (Appendix 1). A passing mark of at least 80% from the theoretical examination would enable the paediatric interns to proceed to the practical session. A repeat session was planned should the paediatric interns fail to attain the minimum required scores.

The practical, hands-on session was conducted by paediatric registrars and/or paediatricians in a 1:5 ratio to the paediatric interns. During this hands-on session, a formal training was conducted on basic clinical skills in performing venepuncture, intravenous cannulation, orogastric tube insertion and tape removal. The rationale of the swaddling blanket and non-nutritive sucking use was highlighted and proper technique was demonstrated during the practical session.

The interventional strategies were carried out over a two-month period and paediatric interns were required to undergo the privileging programme at least once during their rotation in Department of Paediatrics, HTF.

## Results

Our post-intervention study successfully recruited 163 neonates over a two-month duration. Venepuncture was the most commonly performed routine minor procedure (n=110, 67.5%), followed by intravenous cannulation (n=20, 12.3%), tape removal (n=32, 19.6%) and orogastric tube insertion (n=1, 0.6%).

The intervention programme revealed a significant reduction of neonatal painful experience during routine minor procedures from 49.7% to 17.8%, $\chi 2$ (df=1, n=159) = 35.918, $p<0.001$, a surplus from the standard set of 20%, as observed in Table 1.

Following our interventional strategies, 100% of our paediatric interns (n=20) were able to perform correct swaddling technique using the SwaddleMe® Size S and 85% (n=17) of them passed the theoretical examination in their first attempt following the clinical training programme. The remaining interns required a repeat session and passed during the second evaluation.

A detailed analysis on the different types of procedures revealed a statistically significant reduction in neonatal painful experience during routine venepuncture, $\chi 2$ (df=1, n=102) = 23.041, $p<0.001$, but not in the intravenous cannulation and the tape removal groups, as shown in Table 2. Due to the limited sample size, insertion of orogastric tube was not included in the detailed analysis.

## Lessons and Limitations

Our study provided robust local data that solely using a non-pharmacological method is effective in reducing pain in neonates during routine minor procedures, in agreement to other experimental studies (16,21). Our study, however showed that

**Table 1.** Differences in overall pain reduction pre- and post-intervention.

| | No Pain | Pain | *p*-Value |
|---|---|---|---|
| Pre-intervention | 80 (50.3%) | 79 (49.7%) | 0.001* |
| Post-intervention | 134 (82.2%) | 29 (17.8%) | |

*Pearson chi-square test of independence.*
**Statistically significant.*

**Table 2.** Differences in pain reduction based on different types of procedures.

| | | No Pain | Pain | *p*-Value |
|---|---|---|---|---|
| Venepuncture | Pre-intervention | 46 (45.1%) | 56 (54.9%) | <0.001[a]* |
| | Post-intervention | 88 (80.0%) | 22 (20.0%) | |
| Intravenous cannulation | Pre-intervention | 10 (40.0%) | 15 (60%) | 0.526[b] |
| | Post-intervention | 18 (85.7%) | 3 (14.3%) | |
| Tape removal | Post-intervention | 22 (75.9%) | 7 (24.1%) | 0.001[b] |
| | Post-intervention | 28 (87.5%) | 4 (12.5%) | |

*[a]Pearson chi-square test of independence.*
*[b]Fisher exact test.*
**Statistically significant*

venepuncture was the only procedure that was significantly affected through the interventional strategies. The statistically insignificant changes observed in the intravenous cannulation and the tape removal groups may have been contributed by the small sample size.

Additionally, in view of the high turn-over rate of paediatric interns and their sporadic intake schedule, the training and privileging programme for the paediatric interns need to be organised more frequently. However, there was only one paediatrician and three paediatric registrars who were primarily involved with the training session, making understaffing an initial issue for us. Therefore, we re-shuffled the clinical rotation and distributed the workload evenly among all paediatricians, registrars and senior medical officers in the department who were involved in conducting the training session for the house officers.

Apart from that, as only a minimal financial expenditure was needed to cover the cost of 24 swaddling blankets and 24 orthodontic pacifiers with an overall sum of MYR 1,000, the items were personally funded by the team of study associates. The investment was considered necessary and justifiable in view of long-term use of the materials and their significant role in providing our patients with excellent care services.

## Conclusion and the Next Steps

Significant improvement in the reduction of painful experiences in neonates during routine minor procedures in SCN was achieved following this quality improvement project. The success of our interventional programme prompted the development of a local procedural guideline to be implemented during routine minor procedures in neonatal SCN. The guideline incorporates the interventional strategies adopted in this study, including proper swaddling technique and non-nutritive sucking as the non-pharmacological methods of pain relief in neonates during routine minor procedures (Appendix 2).

Our intervention programme can be adopted by other healthcare facilities to improve the quality of care in the management of neonates. The training module for the paediatric interns may be expanded to involve the staff nurses and should be regularly organised to ensure continuous good practice and sustenance of knowledge and enforcement.

The policy changes regarding the implementation of the guideline when managing neonates in SCN during routine procedures are currently undergoing local institutional assessment for long-term feasibility. We aim to promote the use of a standardised modified swaddling blanket to ensure that proper swaddling technique is continuously practised. We are currently collaborating with local tertiary institutions majoring in tailoring and fashion industry to improvise the existing hospital conventional swaddling blanket to create an adjustable blanket that is easier to use, effective and time-saving. Should the collaborative effort produce fruitful results, healthcare policy changes may be proposed to the higher level in using an improvised, adjustable swaddling blanket to ensure proper swaddling technique is practised throughout neonatal centres nationwide.

In the future, we aim to involve other categories of neonates in our project, such as premature babies who are known to be more sensitive towards pain and stress. We also aim to include other routine painful procedures, including heel-prick testing for glucose monitoring and intramuscular vaccinations. Incorporation of pharmacological methods may also be feasible with adequate funding in the future.

## Acknowledgements

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## Conflict of Interest

The authors have no conflict of interest to disclose.

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## Appendix 1

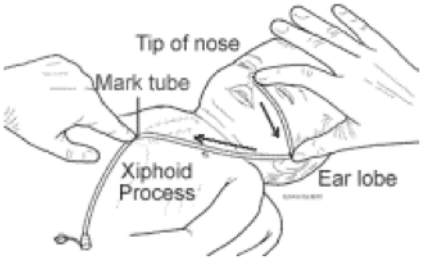
**ASSESSMENT FOR PAEDIATRICS HOUSE OFFICERS**
PAEDIATRICS DEPARTMENT
HOSPITAL TUANKU FAUZIAH, KANGAR, PERLIS

Name : _____ Date : _____

*Please encircle your answer*

PART I: CLINICAL PROCEDURE TECHNIQUES

1. This is the correct way to measure approximate length of Ryle's tube prior insertion T/F




2. 24-G intravenous cannula is purple in colour T/F
3. Drop method is commonly used when withdrawing blood in paediatrics setting T/F
4. Applying alcohol swab must be followed by air-dry for 10 seconds to ensure proper disinfectant T/F
5. The vein must be visualized before a needle is pricked into the skin T/F

PART II: PAIN RELIEF MODALITIES DURING ROUTINE MINOR PROCEDURES

6. Neonates nervous system is underdeveloped that renders them incapable to perceive pain T/F
7. Non-nutritive sucking is an effective, non-pharmacological method of pain relief in neonates T/F
8. Improper swaddling technique adds risk to the development of hip dysplasia T/F
9. Minor procedure can cause pain in neonates T/F
10. Neonatal pain has long-term adverse effects T/F
11. Neonates are more sensitive to pain than older children and adults T/F
12. Pharmacologic/non-pharmacologic interventions are necessary even though many procedures can be completed quickly. T/F
13. Parents are emotionally affected by the pain their infant may be experiencing T/F
14. Parents should be involved with the care and comfort of their infant during painful procedures T/F
15. Non-pharmacological pain management is effective in neonatal pain management. T/F

## Appendix 2

**STEP-BY-STEP PROTOCOL FOR PAIN MANAGEMENT IN NEONATES DURING ROUTINE MINOR PROCEDURE IN SCN**

Pre-heat radiant warmer in servo-controlled baby mode

↓

Place the opened SwaddleMe® blanket under the radiant warmer in T-shape.
Place neonate on the blanket. Identify which limb to be used in procedure.
Attach SpO2 probe to any free limb (not used in procedure).

↓

Tuck baby legs inside the pouch.
Align baby shoulders with the top of open wrap. Leave out the limb that will be used in the procedure.

↓

Keep the elbow extended, forearm pronated and shoulder adducted.
Wrap the left wing over baby's torso and tuck around baby's opposite arm.
Open fabric patch on the underside of the left wing and secure velcro to top of leg pouch

↓

Place right wing over left and secure opened Velcro tabs to fabric patch on left wing.
The wings should be snug, not tight, over baby's chest

↓

Allow baby to suck on Avent® orthodontic pacifier for 1-2 minutes.
Make sure the baseline HR and SpO2 is achieved before starting the procedure

↓

Upon completion of procedure:
- Gently remove the blanket
- Gently tuck away pacifier

↓

Pacifier is cleaned with specialized liquid cleanser and rinsed dry
Place the dried pacifier in the dedicated bag
Blanket is kept clean, folded and kept in the specialized compartment
- Dirty blanket (i.e. from feces, milk curds) will be put away for proper cleaning
- Blanket will be used up to three consecutive babies and will be put aside for cleaning

↓

Place baby back in designated cot

# REDUCING THE FAILURE RATE OF OCULAR PROSTHESIS AT HOSPITAL SULTANAH AMINAH

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## Abstract

The Department of Oral & Maxillofacial Surgery at Hospital Sultanah Aminah, Johor Bahru started managing patients who lost their eyeballs with ocular prosthesis in 2013. Unfortunately, there was an increasing trend of failed ocular prosthesis from 2013-2015. The failure rate went from 28.6% in 2013 to 40% in 2014 and increased to 44.4% in 2015. Failed ocular prosthesis not only leads to dissatisfied patients but also an increase in cost due to redoing of prosthesis. The objective of this project was to reduce the incidence rate of failed ocular prosthesis. A failed case is when the prosthesis does not pass the issue stage and has to be redone from the beginning. The standard failure rate is 0%, as the average number of cases per year is only about 10 cases. We determined the contributing factors of failed ocular prosthesis by analysing retrospective data from patients' dental and lab records. This was followed by a self-administered questionnaire on reasons for failed cases which was distributed among the dentists and lab technicians in our department. The contributing factors that were identified included insufficient knowledge or skill of dentist and lab technicians in the construction of the ocular prosthesis, as well as improper screening of new cases which was the main factor of all the failed cases. The strategies for change included improving the process of care by creating a checklist for proper screening of new patients, mentoring of new staff, and continuous training on construction of ocular prosthesis, Fabricated Iris Mould innovation technique and early referral for insertion of eye conformer. The interventions that were implemented reduced the failure rate to 20% in 2016 followed by 0% in 2017, 2018 and 2019. Ongoing efforts are being done to replicate this project in other Oral & Maxillofacial Surgery clinics in Johor.

**KEYWORDS:** Ocular prosthesis, failure rate, Fabricated Iris Mould, eye conformer

## Problem

Hospital Sultanah Aminah, Johor Bahru (HSAJB) is the official state hospital of Johor. HSAJB accepts referrals from primary and secondary level government healthcare centres, as well as from private healthcare centres. In our Oral and Maxillofacial Surgery (OMFS) department at HSAJB, we receive referrals from external and internal sources, including from the ophthalmology department for ocular prosthesis for patients who have undergone evisceration, enucleation or exenteration of the eye. Our department receives an average of 10,000 patients per year with variable conditions and illness related to OMFS, but the number of patients referred for ocular prosthesis averages only about 10 per year.

Despite the small number of patients referred for ocular prosthesis, we noticed an increasing trend of failed cases of ocular prosthesis. Total patients with failed ocular prosthesis increased from 28.6% (two out of seven) in 2013, to 40% (four out of ten) in 2014. In the year 2015, the failed ocular prosthesis rate increased to 44.4% (four out of nine). This showed an exponential increase in the failure rate of ocular prosthesis from the year 2013 to 2015.

A failed ocular prosthesis may lead to dissatisfied patients, which could affect their social and psychological wellbeing, and they could become a potential complaint or file a lawsuit against our department. A failed ocular prosthesis could also be a potential source of infection and irritation and lead to a significant increase in cost due to repairing or redoing the prosthesis. The cost of constructing an ocular prosthesis can amount up to MYR 5,000.00, thus, redoing an ocular prosthesis case would double the cost. Previously, patients had to pay a MYR 100.00 fee for the construction of an ocular prosthesis. Fortunately, this fee is currently fully subsidised and patients do not need to pay for the ocular prosthesis construction according to the Fee Order (Medical) 2017 Ministry of Health Malaysia. This highlights the vast gap in the cost needed to construct one ocular prosthesis, compared to the zero-amount charged to patients to obtain one. Therefore, it is crucial not to have a failed ocular prosthesis, which would lead to an increase in the already high cost. The process of constructing an ocular prosthesis is very complicated especially during the lab processing stage and requires a skilled dental technician who have undergone OMFS post basic training. The aim of this study was to decrease the failure rate of ocular prosthesis at HSAJB to zero percent within one year.

## Background

Eye loss resulting from congenital malformation, tumour treatment, or trauma may lead to social, family and psychiatric problems. A mutilated face can affect the patient's self-esteem due to difficulty in establishing emotional ties, new life style, insecurity, and rejection, as shown in a study where an average of 60% of patients suffering from eye loss exhibited these symptoms (1). An ocular prosthesis, artificial eye or glass eye, is a type of craniofacial prosthesis that replaces an absent natural eye following an orbital enucleation, orbital evisceration, or orbital exenteration (2,3). Ocular prosthesis differs from ocular or orbital implants where an ocular prosthesis is made purely from polymethylmethacrylate (PMMA) material with no points for implant insertion. A study done in South Korea showed that 71.8% of the patients were satisfied with their initial ocular prosthesis post-evisceration or post-enucleation (4).

Limited literature is available on the average failure rate of ocular prosthesis in a community. However, according to Leatherbarrow et al., out of 44 patients who received ocular prosthesis at a hospital in Manchester, Britain, six patients presented with failed ocular prosthesis (13.6% failure rate) where the reason of failure was their eye socket anatomy and they needed a secondary surgery to repair the eye socket to redo the ocular prosthesis successfully (5). Another study done at Jules Stein Eye Institute; Los Angeles showed a zero percent failure rate (zero out of nine patients) who were reviewed on average of four years (6). Compared to these studies,

our department had an alarmingly high failure rate at 44.4%. As stated previously, only a few studies on successful ocular prosthesis has been reported in literature, hence providing limited evidence on successful ocular prosthesis strategies.

## Measurement

The general objective of this project was to reduce the incidence rate of failed ocular prosthesis at HSAJB. The specific objectives included identifying contributing factors of failed ocular prosthesis, implementing remedial actions that address the contributing factors and evaluating the effectiveness of the remedial actions taken.

The indicator used in this study was the failure rate of ocular prosthesis at HSAJB. The calculation formula for the indicator was:

$$= \frac{\text{Number of failed cases of ocular prosthesis issued for a particular year}}{\text{Total number of all selected cases for ocular prosthesis for the same particular year}} \times 100\%$$

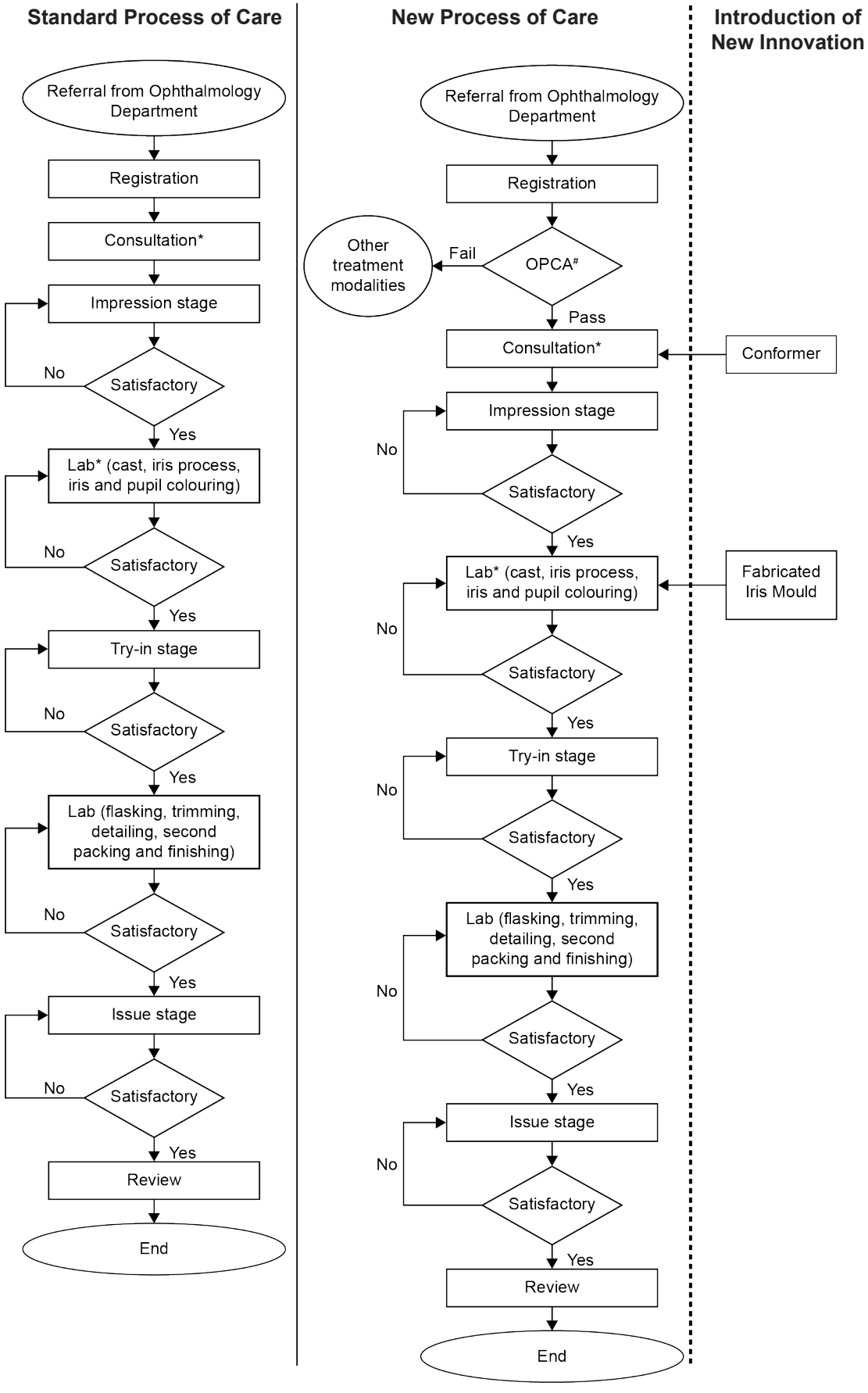
According to DM Meisler et al., (7) an ocular prosthesis fails when it causes irritation or infection in an eye socket. In our department, an ocular prosthesis was considered failed when an ocular prosthesis did not pass the issue stage (as stated in the Process of Care (POC), Figure 1) of the prosthesis and the whole clinical and lab process must be repeated to re-issue the ocular prosthesis. According to our Model of Good Care (MOGC, Table 1), during the issue stage, the dentist and dental technician need to ensure that the ocular prosthesis fits well in the patient's eye socket, appears natural, the color, shape and position of the iris on the ocular prosthesis is similar to the adjacent eye, and the ocular prosthesis does not cause irritation to the patient. The standard failure rate is 0% as the total number of issued ocular prosthesis averages to only about 10 cases per year. The standard was determined by our Head of Department with the consensus of our OMFS specialist.

This quality improvement study was conducted in the OMFS Department in HSAJB from June 2015 to December 2019. Data was collected by reviewing dental records of ocular prosthesis patients from 2013 to 2019 (LP6 Dental Laboratory card and LP8 Dental Clinical card). Data was also collected every time an ocular prosthesis patient came for their appointment. The inclusion criteria included any ocular prosthesis cases in HSAJB, which was referred to our department. Exclusion criteria was any ocular prosthesis cases in HSAJB where the patient failed to attend their appointment during any stage of their treatment.

## Initial Assessment of the Problem

A verification study was done from June 2015 to November 2015 where the failed ocular prosthesis cases were analysed to determine the reasons of failure by reviewing the patients' dental records. It was determined that 90% (nine of out 10 cases) of the failed cases were due to anatomical reasons, while 10% (one out of 10 cases) of the failed cases were because of psychological reasons (Table 2). Further analysis was done on poor anatomical eye socket cases to determine the factors that caused this problem.

In December 2015, a survey was conducted by distributing the questionnaire among the three specialists, seven Dental Officers, Officers, seven First Year Dental Officers (FYDO) and three Dental Technicians from the OMFS department (total n=20). The questionnaire listed four potential contributing factors where the respondents had to score each factor from one to five, with five score being the highest potential factor.




** Critical steps*
*# Ocular Prosthesis Criteria Assessment*

**Figure 1:** Standard Process of Care versus New Process of Care.

**Table 1:** Comparison of Model of Good Care Before and After Remedial Measures.

| No. | Process | Criteria | Standard | Verification | Cycle 1 | Cycle 2 |
|---|---|---|---|---|---|---|
| 1. | Registration | Ensure the correct patient is referred to the OMFS department | 100% | 100% | 100% | 100% |
| | | Ensure the details of the patients are properly registered and documented | 100% | 100% | 100% | 100% |
| 2. | Consultation | To determine if patient is both physically and mentally fit for ocular prosthesis treatment | 100% | 50% | 100% | 100% |
| | | To examine the condition of the eye socket prior to treatment. | 100% | 50% | 70% | 100% |
| 3. | Impression stage | Impression taken using alginate | 100% | 70% | 70% | 100% |
| | | To ensure all borders of the eye socket taken properly | 100% | 70% | 70% | 100% |
| 4. | Lab (cast, iris process, iris & pupil colouring) | To cast impression with methacrylate resin | 100% | 70% | 70% | 100% |
| | | To fabricate iris & pupil by taking into account the appearance of the adjacent eye | 100% | 50% | 50% | 100% |
| 5. | Try-in stage | To ensure the wax try-in fits properly in the eye socket and does not displaced | 100% | 70% | 70% | 100% |
| | | To ensure position, colour and shape of iris is the same as the adjacent eye | 100% | 70% | 70% | 100% |
| 6. | Lab (flasking, trimming, detailing, second packing & finishing) | To invest, cure, detailing, second invest process and finishing of prosthesis | 100% | 70% | 80% | 100% |
| | | To ensure anatomical characterization was done using acrylic paints to simulate the veins and follow the actual colour of adjacent eye | 100% | 70% | 80% | 100% |

| No. | Process | Criteria | Standard | Verification | Cycle 1 | Cycle 2 |
|---|---|---|---|---|---|---|
| 7. | Issue stage | Ensure the ocular prosthesis fits well in the eye socket and appear natural | 100% | 70% | 75% | 100% |
| | | Ensure the colour, shape and position of the iris on the ocular prosthesis is similar to the adjacent eye | 100% | 76% | 85% | 100% |
| | | Does not cause irritation to patient | 100% | 70% | 80% | 100% |
| 8. | Review stage | To review the patient's compatibility with the ocular prosthesis | 100% | 100% | 100% | 100% |
| | | To see if any problems arise such as irritation, looseness of ocular prosthesis or others | 100% | 100% | 100% | 100% |

**Table 2:** Category of failed ocular prosthesis at HSAJB 2013-2015.

| Year | MRN Patient | Age | Type of ocular prosthesis | Reason of Failure |
|---|---|---|---|---|
| 2013 | A1 | 8 | Left eye prosthesis | Growth in eye socket |
| 2013 | A2 | 9 | Left eye prosthesis | Too shallow eye socket |
| Total number of failed ocular prosthesis in 2013: 2. Total issued: 7 | | | | |
| 2014 | B1 | 59 | Right eye prosthesis | Socket not properly healed |
| 2014 | B2 | 30 | Right eye prosthesis | Too deep eye socket |
| 2014 | B3 | 64 | Left eye prosthesis | Growth in eye socket |
| 2014 | B4 | 10 | Right eye prosthesis | Patient mentally ill |
| Total number of failed ocular prosthesis in 2014: 4. Total issued: 10 | | | | |
| 2015 | C1 | 35 | Left eye prosthesis | Eye socket space too big |
| 2015 | C2 | 11 | Left eye prosthesis | Sutured eye socket |
| 2015 | C3 | 44 | Right eye prosthesis | Eyeball still present in socket |
| 2015 | C4 | 16 | Right eye prosthesis | Too much eye discharged |
| Total number of failed ocular prosthesis in 2015: 4 Total issued: 9 | | | | |

The cumulative points for each question would determine the importance of the contributing factor. From the survey, it was determined that improper screening process was the main contributing factor (90 points), followed by lack of knowledge in construction of ocular prosthesis (75 points), poor skills in clinical procedure (60 points) and finally, poor material used for ocular prosthesis (30 points).

The POC (Figure 1) was also evaluated and we found two most critical processes in the POC that did not comply with the MOGC standard (Table 1). The first was Consultation, where the clinical operator was supposed to determine if the patient was both physically and mentally fit for ocular prosthesis treatment, as well as examine the condition of the eye socket prior to treatment. We only managed to achieve 50% for this process. The second critical process, Lab (cast, iris process, iris and pupil coloring) is where the Dental technician needed to cast an impression with methacrylate resin (achieved only 70%) and fabricate the iris and pupil by taking into account the appearance of the adjacent eye (achieved only 50%). Other critical steps in the MOGC also did not obtain 100%.

After analysing all the data, the main contributing factors were determined. The first contributing factor was the improper screening process; there was no guideline on proper screening for ocular prosthesis cases, which led to cases of patients with improper orbital anatomy and poor psychological condition being accepted for ocular prosthesis. We also had other issues such as immature post-operative referral and high patient's expectations upon initiation of treatment. The second contributing factor was the lack of knowledge or skill in construction of ocular prosthesis, inexperienced Dental Technicians, and complicated lab procedures. Finally, the third contributing factor was insufficient skill or experience in taking impression for ocular prosthesis, and inexperienced Dental Officers. The lack of Continuous Dental Education (CDE) was also apparent for all the contributory factors, which led to improper screening, lack of skill during impression taking and during construction of ocular prosthesis.

## Strategy

We conducted two phases of remedial measures. The first phase was from January 2016 to December 2016 and the second phase was from January 2017 to December 2017.

*a) First Phase:*

During the first phase of remedial measure, we tackled the improper screening process factor by having a CDE in January 2016 on proper screening of patients suitable for ocular prosthesis. This CDE involved New Dental Officers from the OMFS department as well as new Medical Officers from the Ophthalmology Department, HSAJB. This was followed by a screening checklist, Ocular Prosthesis Criteria Assessment (OPCA, Appendix 1), that was created and distributed to the OMFS department on 10 January 2016, which functioned as a guideline in referring patients for ocular prosthesis. This checklist was reviewed and approved by our OMFS Head of Department and Specialists. The OPCA screening checklist acted as a "gatekeeper" where any patients that required an ocular prosthesis must pass the checklist before they could be listed on our waiting list for construction of the ocular prosthesis. The checklist contained two sections; the first section assessed the patient's psychosocial and physical state to determine if he or she was mentally stable and in good physical state to be selected for ocular prosthesis treatment. The second section was an assessment of the eye socket to evaluate if it was in optimal condition for ocular prosthesis. Patients with conditions such as residual, growth, tissue tag or sutures in the eye socket were considered non-optimal and should not be issued with ocular prosthesis. Depth of eye socket and width of the eye fissure was also considered in the checklist. This ensured the patient's eye socket was in an optimal condition prior to the start of the treatment.

Next, we tackled the lack of knowledge or skill in construction of ocular prosthesis factor by having a CDE in April 2016 on construction of ocular prosthesis for new dental technicians involved in ocular prosthesis construction. We also started a mentoring program for new staff, where the new staff (usually dental technicians) would be mentored and supervised by a senior staff (supervisor). The mentoring program was carried out throughout 2016.

*b) Second Phase:*

After re-evaluation of the first phase, despite the interventions done, we noticed that there were still cases with improper orbital anatomy, and complicated lab procedures were still an issue. So, in the second phase, we continued all remedial measures that were conducted in the first phase with an addition of two new remedial measures. The first strategy tackled the improper orbital anatomy by having patients being referred earlier for insertion of eye conformer, especially for patients with post evisceration or enucleation of the eye. By having an eye conformer (pre-shaped clear acrylic shell) inserted immediately post evisceration or enucleation of the eye (within two weeks), it helped hold the shape of the eye socket for easy insertion of the ocular prosthesis later upon construction. The second remedial measure tackled the complicated lab procedures factor by the innovation of a prefabricated iris mould, Fabricated Iris Mould (FIM, Table 3). During the iris process stage of the ocular prosthesis construction in the lab, the iris sizes are usually limited due to the limited resources in purchasing the original cast to create the synthetic iris. By having this FIM innovation, where we created our own synthetic iris with variable iris sizes, we not only drastically reduced the overall cost of the ocular prosthesis but also eased the lab procedure as the FIM method was a less sensitive technique. By the end of the second phase, we had created a new, more efficient POC (Figure 1) compared to the standard POC.

## Results

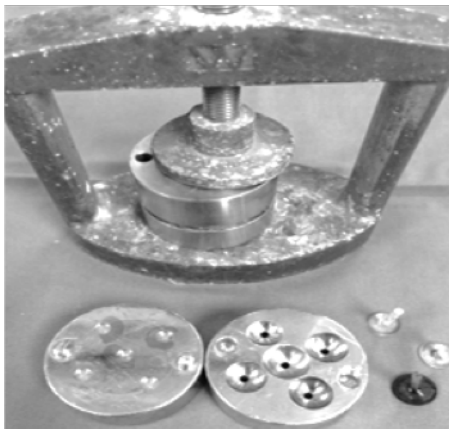
The first remedial measure phase was completed in December 2016 and was evaluated in January 2017. The failure rate reduced from 44.4% from the previous year to 20% (three out of 15) in 2016. Despite the lower failure rate, we still did not manage to obtain our target, thus the failed cases were re-evaluated. Two cases had shallow eye socket (improper orbital anatomy) as reasons of failure, and one case had improper size of iris (limited iris size available in the lab). Reassessment of the MOGC (Table 1) showed improvement but it was still not optimal. Since we were unable to achieve a zero percent failure rate, we proceeded with another remedial measure phase for another year.

After implementation of two additional remedial measures during the second phase, we managed to obtain zero percent failure rate (zero out of 8). Re-evaluation of critical steps implementation in the MOGC also showed 100% achievement for all steps (Table 1). All remedial measures were continued in the subsequent years and we managed to maintain zero percent failure rate in 2018 and 2019 (Figure 2).

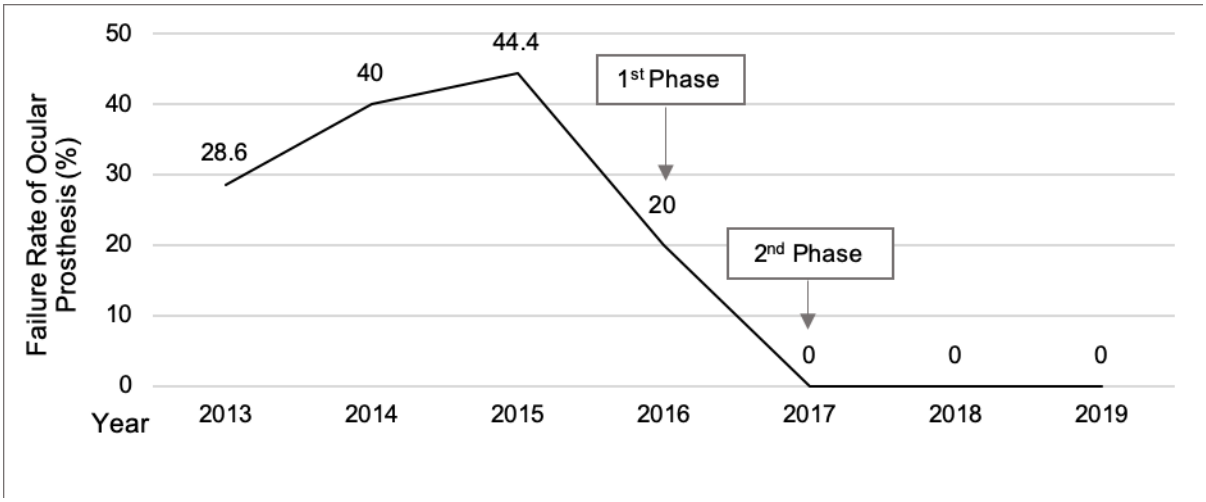
## Lessons and Limitations

This project highlighted the many issues that our OMFS department faced in providing ocular prosthesis treatment for patients, which caused an increase in failure rate of ocular prosthesis at HSAJB during the first few years. This was perhaps due to fact that the OMFS department just started ocular prosthesis treatment in 2013, where all the staff and doctors were new to this treatment. There was also no national guideline in ocular prosthesis referral of treatment which led to this problem. By initiating this QA project, we managed to improve the treatment of ocular prosthesis patients, thus increasing patients' satisfaction and their overall quality of life.

**Table 3:** Comparison between standard lab method with FIM method.

| Before FIM | After FIM |
|---|---|
|  |  |
| Limited iris size | Variable iris size |
| High risk of iris post breakage | Eliminate risk of iris post breakage |
| Difficulty in iris removal from mould | Simplified iris removal from mould (less technique sensitive) |
| Whole process of iris construction cost MYR 3,007.60 | Whole process of iris construction cost MYR 5.70 |

*FIM: Fabricated Iris Mould.*




| Year | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
|---|---|---|---|---|---|---|---|
| No. of issue | 7 | 10 | 9 | 15 | 8 | 11 | 8 |
| No. of failure | 2 | 4 | 4 | 3 | 0 | 0 | 0 |
| Failure rate | 28.6% | 40% | 44.4% | 20% | 0% | 0% | 0% |

**Figure 2:** Failure rate of ocular prosthesis at HSAJB from 2013 – 2019.

By having a zero percent failure rate, we managed to save a huge amount in constructing ocular prosthesis. Since the project started, we managed to save up to MYR 50,000, and by the end of the project we reduced the cost of one ocular prosthesis from approximately MYR 5,000 to MYR 2,000, effectively saving around MYR 3,000 per ocular prosthesis.

We also acknowledge certain limitations in our project where our remedial measures might only be applicable to our department and hospital. Further review of feasibility and suitability of the remedial measures will be needed if implementation of these remedial measures at higher level (for example national level) is to be considered. Our data is also limited to be used in Malaysia as the treatment of constructing ocular prosthesis in other countries is not limited to the OMFS Department.

## Conclusion and Next Steps

This project managed to identify the factors that led to the increasing failure rate of ocular prosthesis at HSAJB. By formulating and implementing relevant remedial measures that tackled the identified factors, we managed to reduce the failure rate from 44.4% to the standard of zero percent. By doing so, we not only managed to provide the best treatment for patients in need of an ocular prosthesis, but also reduced the overall cost of constructing the ocular prosthesis via the FIM innovation. By having zero percent failure rate, we also prevented doubling the cost of constructing an ocular prosthesis for the same patient.

To maintain zero failure rate for ocular prosthesis, the project is still being conducted and monitored. Therefore, ongoing efforts must be maintained to further enforce and advocate the preventive measures, as well as maintain zero percent failure rate of ocular prosthesis. This project was presented to all Johor District Dental Officers on 8 April 2019 for suggestion of project implementation in all OMFS departments in the state of Johor. This project will also be evaluated by the headquarters for potential national-level replication.

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## Conflict of Interest

None.

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## Appendix 1

**OCULAR PROSTHESIS CRITERIA ASSESSMENT (OPCA)**

| | | | |
|---|---|---|---|
| NAME | : | AGE | : |
| NRIC NO. | : | RACE | : |
| SEX | : | OCCUPATION | : |
| ADDRESS | : | DATE | : |
| EYE HISTORY | : TRAUMA/NON-TRAUMA (OTHERS: ……) | | |

**SECTION A: PATIENT'S PSYCHOSOCIAL & PHYSICAL STATE**

- Mentally Stable ☐
  - Functioning at satisfactory level of emotional and behaviour with/without underlying mental illness (able to work and live)
- Cooperative ☐
  - Able to obey command and adapt to changes
- Loss of unilateral eye ☐

*Patient has to **fulfil all criteria** in **Section A**. Kindly reassess the need or appropriateness for ocular prosthesis if criteria are not met.*

**SECTION B: CONDITION FOR EYE SOCKET FOR OCULAR PROSTHESIS**

I. a. Residual eye in socket ☐
   b. Growth of soft tissue/present of tissue tag in eye socket ☐

*For patient with above criteria, surgical removal and review is needed, patient need to be referred back.*

II. a. Sutured eye socket ☐
    b. Eye socket swelling ☐

*For patient with above criteria, to be referred back for further review.*

III. a. Eye socket too deep (socket depth >12mm) ☐
     b. Eye socket swelling ☐

*For patient with above criteria, need implant prior ocular prosthesis*

IV. a. Drop lid ☐
    b. Eye size too small compare to contralateral (socket depth/fissure width <8mm) ☐

*For patient with above criteria, ocular prosthesis can be made but with unfavourable aesthetic. Explanation to patient is needed prior to start of treatment.*

Attending Doctor

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# IMPROVING THE APPROPRIATENESS OF THERAPEUTIC DRUG MONITORING SAMPLING IN HOSPITAL SULTANAH NUR ZAHIRAH, KUALA TERENGGANU

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## Abstract

Therapeutic drug monitoring (TDM) is a valuable clinical tool in optimisation of drug regimens. However, improper utilisation of TDM may lead to significant resource wastage and expose patients to avoidable trauma, toxicity, therapeutic failure and prolonged hospitalisation. This study aimed to reduce the percentage of inappropriate TDM sampling to our proposed standard of less than 20% within a four-month intervention period. A cross-sectional study was undertaken from January to December 2015 at the inpatient setting of Hospital Sultanah Nur Zahirah. Gentamicin and Vancomycin analytes were studied because these analytes accounted for 69.2% of total samples received in 2014. TDM Monitoring Form was used to collect sampling and dosage information to assess sampling appropriateness. A closed-ended self-administered questionnaire was distributed to a group of medical doctors to assess their knowledge on appropriate Gentamicin and Vancomycin TDM sampling method pre- and post-intervention. Prior to the intervention phase in October to December 2014, 79.4% of TDM were inappropriately sampled. The main contributing factors were inadequate knowledge among medical doctors, lack of sampling reminders for new TDM requests, and misunderstanding on sampling information for repeated TDM requests. 60-minute face-to-face educational sessions on TDM sampling method were conducted specifically for staff at the General Medical and Paediatric Departments, and two continuing medical education (CME) slots were held at the hospital level. Guidelines on TDM sampling was initiated and laminated copies were distributed to all wards. Implementation of TDM Alert System which consisted of digital reminders and physical stickers was also introduced. The interventions were able to reduce the inappropriate sampling percentage from 79.4% to 41.8% post-intervention, and to 19.1% in the recent monitoring phase of January until June 2019. Continuous close monitoring and sustainable implementation of the measures are vital as TDM sampling appropriateness may affect clinical interpretation of the results.

**KEYWORDS:** Therapeutic drug monitoring, sampling, appropriateness

## Problem

Improper utilisation of therapeutic drug monitoring (TDM) is inclusive of inappropriateness in its indication, sampling time and application of results. This may lead to significant wastage of resources and expose patients to trauma, toxicity, therapeutic failure and prolonged hospitalisation. In 2012, inappropriate Vancomycin TDM alone was reported to result in an excess of USD 13,080 (MYR 53,366) per year of unnecessary hospital expenditure in the United States of America (1). As a comparison, in 2014, inappropriate sampling of Gentamicin and Vancomycin TDM was associated with an extrapolated annual avoidable cost of MYR 21,664 in Hospital Sultanah Nur Zahirah (HSNZ). This highlights the importance of an improvement of quality in our institution where resources are highly valued.

HSNZ is a state general hospital situated in the district of Kuala Terengganu with a population of 343,282 people. HSNZ has a maximum capacity of 1,107 beds and 43 wards. HSNZ serves as a reference hospital for district hospitals and health clinics throughout the state of Terengganu with an estimated population of 1,250,000.

Pharmacy Department is one of the key clinical support units in HSNZ. This department provides a wide range of pharmaceutical care services including ambulatory pharmacy, inpatient pharmacy, ward pharmacy, clinical pharmacokinetics, manufacturing, logistics, pharmacy resources and information centre. The Clinical Pharmacokinetic Unit (CPU) is responsible for processing TDM requests i.e. screens TDM requests and blood samples, interprets the results based on patients' clinical status, communicates interpretation of the results, and recommends appropriate action to the requesting physician (2). The unit is led by a pharmacist and supported by provisionally registered pharmacists. In HSNZ, sample analysis is carried out by the Pathology Department. Results and recommendations of TDM requests will be relayed between laboratory staff to pharmacists and ultimately to medical doctors through the Laboratory Information System (LIS) and Hospital Information System (HIS), respectively. As a reference hospital, the unit accepts both internal and external TDM requests, including from district hospitals and health clinics. In 2014, CPU received a total of 5,327 TDM requests of 13 different analytes of narrow therapeutic window drugs (3) including Amikacin, Gentamicin, Vancomycin, Carbamazepine, Digoxin, Phenobarbitone, Valproic Acid, Cyclosporine, Methotrexate, Phenytoin, Theophylline, Paracetamol and Salicylate. Out of these samples, 69.2% were Gentamicin and Vancomycin requests, and were mainly received from General Medicine and Paediatrics Department.

During the pre-intervention phase of this study in HSNZ, 79.4% (n=677/853 samples) of the internal TDM samplings were inappropriate, which highlighted the urgent need to solve the problem. This study was designed to reduce the inappropriateness of internal TDM sampling in HSNZ to less than 20% within a 4-month intervention period (a 50% reduction from a local study by Hamzah et al. (4) which reported 45.2% of inappropriate sampling).

## Background

TDM is an important pharmaceutical care service for optimisation of drug regimens with a narrow therapeutic index. It aids in identifying alterations in drug disposition and possible drug-drug interactions, designing patient-specific drug regimen and minimising adverse effects (5). Appropriate sampling of TDM is vital as accurate interpretation of TDM results by TDM pharmacists depends on the concise information on the sampling (6,7).

A local cross-sectional study in 2008 evaluated TDM sampling inappropriateness in HSNZ. Eighty four TDM requests, including Digoxin, Gentamicin and antiepileptic analytes were screened and 45.2% of them were found to be inappropriately sampled (4). Since ordering of TDM requests by a computerised order system had yet to be available during that time, the study suggested comprehensive and long term educational programs for medical doctors and nurses, along with active roles of ward pharmacists during clinical rounds as the corrective intervention

(4). Another study conducted at the Singapore General Hospital in 2014 stated that 61.5% of Vancomycin TDM samples were inappropriately withdrawn (8). An analysis of the inappropriately sampled Vancomycin showed 41 unnecessary dose withholds, 24 dose changes, and 102 unchanged doses. The associated cost due to inappropriate interpretation was USD 7,286 (MYR 29,727) (8).

Through an audit in a Hong Kong government hospital laboratory, Kwok et al. (9,10) found multiple reasons for inappropriate orders of laboratory tests. These included medical doctors making a mistake, inadequate knowledge on appropriate use of the tests, lack of experience, and repetitive ordering of tests prior to checking the results of the previous test.

Effective educational programme and accessible guideline for TDM sampling are vital. By educating nurses and phlebotomists about the appropriate timing of Vancomycin sampling, the timing appropriateness improved significantly from 37% to 78% post intervention (11). The percentage of Vancomycin trough sampled at steady state concentration also increased from 36% to 55% (11). Intervention of 60-minute face-to-face educational sessions and provision of printed Vancomycin dosing and monitoring guideline to junior medical officers and pharmacists increased the appropriate sampling time from 72.6% to 80.6% (12).

Utilisation of digital reminders for TDM tests ordered through computerised physician order system is another means to improve the appropriateness of TDM sampling. In a study conducted in Brigham and Women's Hospital in Boston, Massachusetts in 2011, an information technology based intervention that provided educational instructions and linked the timing of medication administration to nurses who were responsible for Vancomycin trough blood withdrawal reduced the Vancomycin timing errors percentage from 39% to 32% (6). A pop up alert message when Vancomycin test was ordered including a timing guide and a justification for routine monitoring increased the percentage of appropriate Vancomycin trough order from 58% to 68% (13).

## Measurement

The primary outcome of the study was the percentage of inappropriate TDM sampling, calculated as the number of inappropriate TDM samples over the total number of TDM samples received. Inappropriate sampling was defined as TDM blood withdrawal which was inconsistent with our local TDM sampling guidelines in terms of timing, completeness and steady state achievement at point of sampling (14). The study included new and repeated TDM requests. New TDM requests are samples from patients who have not been sampled for TDM investigations, while repeated TDM requests are samples withdrawn based on recommendation of previous TDM result interpretation. Each TDM request was clerked by pharmacists at CPU using HSNZ TDM Monitoring Form before results interpretation was provided. These forms were used as our data collection tool to examine information on sample timing, medication dosing, and time interval.

Initial data was obtained retrospectively with samples received throughout 2014. It was found that out of a total of 5,327 samples and 13 different analytes, Gentamicin topped the list of the most requested TDM analytes (52.0%; n=2,772), followed by Vancomycin (17.2%; n=916). Therefore, all new and repeated samples of Gentamicin and Vancomycin were included to prevent probable resistant strains that could have resulted from improper sampling. All inpatients were included in the study, except those with stage 5 Chronic Kidney Disease.

A pre-intervention analysis of Gentamicin and Vancomycin TDM samples received between October and December 2014 showed that 79.4% (677/853 samples) of these samples were inappropriately withdrawn. Based on a group consensus, our team agreed to propose a standard of up to 20% of inappropriate sampling based on availability and capability of existing human resource, a 50% reduction from a local study by Hamzah et al. (4) which

reported 45.2% of inappropriate sampling.

## Initial Assessment of the Problem

A cause-and-effect analysis was performed during the problem analysis phase to gain an early understanding on the possible contributing factors to the problem (Figure 1). The identified factors involved inadequate knowledge among medical doctors, lack of sampling reminder for new TDM requests, and misunderstanding of the sampling information for repeated TDM requests.

We started our study by evaluating the knowledge of TDM sampling among medical doctors, as they were responsible for ordering TDM requests on our computerised physician order system of Hospital Information System (HIS) and executing blood withdrawal thus ample knowledge on TDM sampling information is vital. A closed-ended self-administered questionnaire was developed to assess medical doctors' knowledge on Gentamicin and Vancomycin TDM sampling methods pre- and post-intervention. The questionnaire consisted of 10 questions: four questions on sampling time, three questions on sampling components, and three questions on time to steady state. A respondent would be categorised as having 'Good Knowledge' if he/she scores at least 80%. A number of 95 medical doctors responded to the questionnaire and only 61.1% (n=58) of them had 'Good Knowledge' in the pre-intervention phase.

Based on the training record review, there was no documented department-driven seminar or short educational lectures provided to medical doctors from the period of 2012 till 2014. The existing local clinical pharmacokinetic protocol which contained information on sampling, pharmacokinetics, adverse drug reaction, monitoring parameter, dosage and interaction was last reviewed in 2008. In addition to that, a simplified version of the sampling guideline for quick reference to the ward staff was also not available, explaining the reason for a lack of reference for TDM sampling at wards.

Despite having a computerised physician order system of HIS for TDM investigations, there was under-utilisation of digital reminders to guide medical doctors on new and repeated sampling instructions. No planned provision of sampling guide was made available for new TDM requests as information was given upon request by medical doctors and by clinical pharmacists during ward rounds. On the other hand, all repeated TDM requests were dependent on the pharmacy team through phone reminders on the correct sampling time.

## Strategy

Based on the contributing factors identified, four improvement strategies were formulated. An institutional TDM sampling guideline was introduced with specific sampling time and elements (e.g. peak and trough concentrations). The sampling information in the 2008 institutional protocol was improvised based on previously published reference and with input from our TDM pharmacist. The new version was complete with sampling details on timing for steady state achievement for Gentamicin and Vancomycin. Unnecessary TDM sampling of Vancomycin peak concentration was removed. Additionally, the sampling guideline was simplified into a single-page reference and the laminated form of the guidelines was distributed to all wards.

Secondly, the project team provided face-to-face 60-minute educational sessions on Gentamicin and Vancomycin TDM sampling guidelines, especially on its clinical applications to medical doctors. Four sessions were held at different hospital platforms; individual sessions for General Medical and Paediatrics Department staff, and two continuing medical education (CME) slots for hospital staff and medical housemen. Focus was given on the appropriate sampling in terms of specific timing and steady state of Gentamicin and Vancomycin, importance of accurate sampling, and possible complications of non-compliance. The educational sessions received positive feedback from the audience.

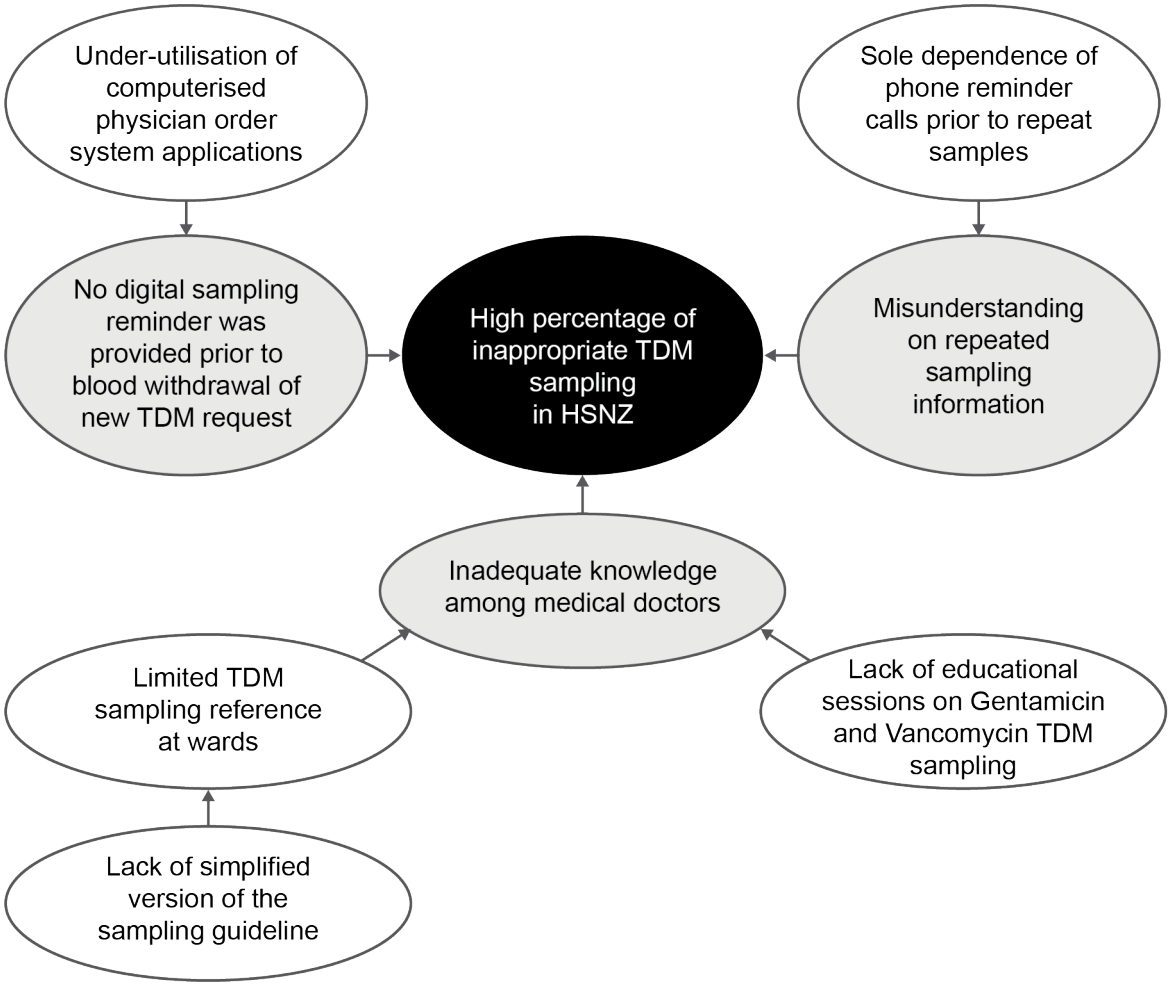


**Figure 1:** Cause-and-effect chart of high percentage of inappropriate TDM sampling.

The senior doctors indicated that the intervention provided them with good insight into the issue and how they could contribute to solving the problem.

The current process of care was reviewed and was found to be insufficient to support a TDM request handling, which led to an appropriate sampling. Thus, the process of care was updated with additions of a few critical steps, particularly in providing sampling reminder (Figure 2).

A reminder system named 'TDM Alert' was created and prompted medical doctors to execute blood withdrawal in new and repeated cases at the right time, with complete TDM request, and after the steady state had been achieved. The reminder would appear at two points of work process prior to blood sampling. The first point was during the ordering step of TDM drugs and request on HIS. An on-screen pop-up would appear to guide medical doctors on the general sampling information for the drug. The second point was when planning for repeated Gentamicin and Vancomycin sampling. To ensure accurate repeated sampling, a physical sticker with the information of planned and actual timing, and elements of repeated blood taking was introduced. This measure, named 'TDM Alert Sticker', would be filled and pasted onto the patient's bed head ticket (BHT) by the CPU pharmacist a day prior to the planned sampling date.

## Results

Each intervention implemented led to a substantial improvement in the percentage of TDM sampling appropriateness.

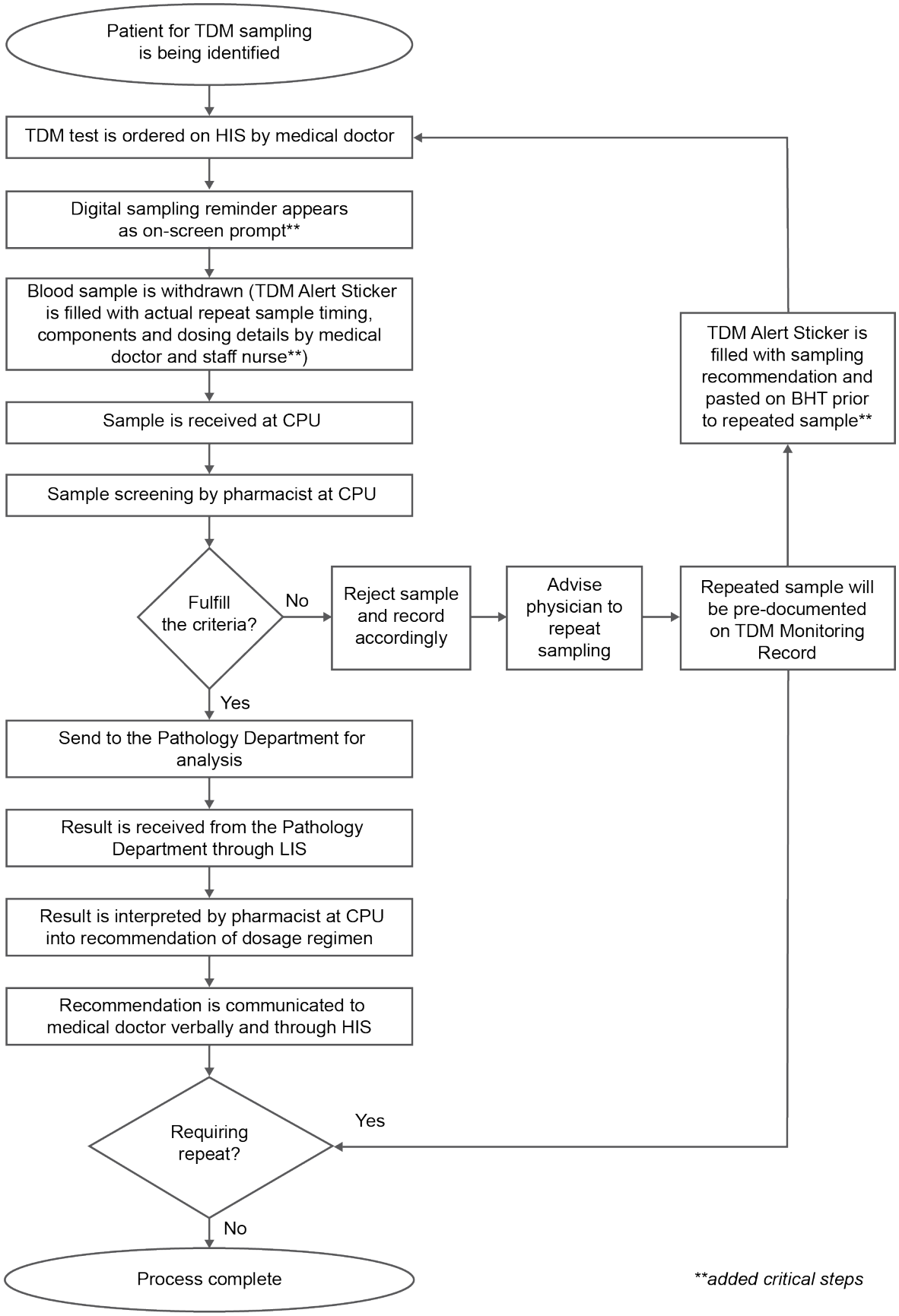


**Figure 2:** Improved standard operating procedure or point of care to enhance TDM sampling appropriateness

The percentage of Gentamicin and Vancomycin TDM inappropriate sampling was reduced to 41.8% (666/1,594 samples) following the intervention between July to December 2015. The monitoring phase continued and recent results showed that the inappropriateness level further decreased to a level lower than the standard set (20% of inappropriate sampling) (Figure 3).

Cost saving was calculated in terms of extrapolated annual avoidable cost attributed to the reagent test kit expenditure. This was inclusive of reagent test kit cost associated with inappropriate sampling (Cost per Gentamicin and Vancomycin test: MYR 8.00). In 2014, the extrapolated annual avoidable cost of inappropriate TDM sampling was MYR 21,664 per year (3-month pre-intervention inappropriate samples of 677) and in 2015, post intervention, the cost reduced by 50.8% to MYR 10,656 per year (6-month post-intervention inappropriate samples of 666).

There was an improvement in the level of knowledge on TDM sampling of Gentamicin and Vancomycin among medical doctors. During the face-to-face educational lectures, medical doctors were requested to answer self-administered questionnaire on Gentamicin and Vancomycin sampling method before and after the session. Of the 95 participants who consisted of 5 specialists, 15 medical officers, and 75 medical housemen, the percentage of medical doctors who had 'Good Knowledge' i.e. a score of at least 80%, increased from 61.1% (58 subjects) to 88.4% (84 subjects) following the intervention.

In addition to that, the project resulted in the pharmacy department being given permanent slots at the medical housemen' orientation week and once-a-year session at the medical housemen' educational slots in HSNZ from 2016. These sessions serve as an update sharing platform on TDM for new medical doctors.

## Lessons and Limitations

Engaging a multi-disciplined team was imperative to initiating and sustaining successful change.

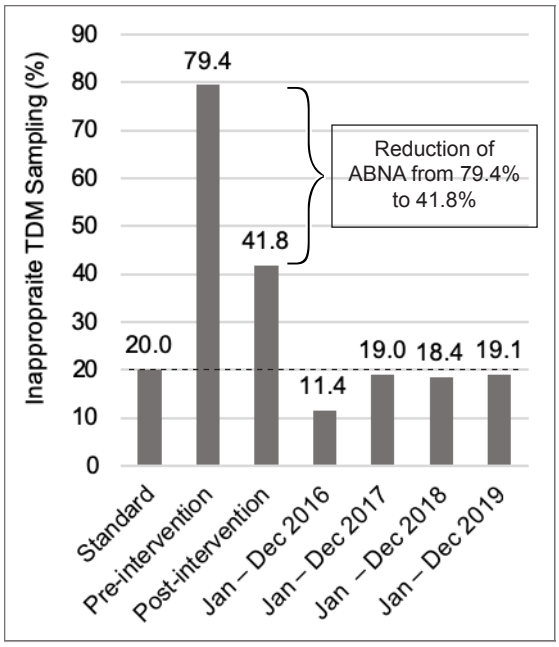


**Figure 3:** Percentage of inappropriate TDM sampling pre (October – December 2014) and post (July – December 2015) intervention phases

Senior doctors played a vital role in encouraging the medical housemen to improve their quality of TDM blood taking. Nurses on the other hand assisted with blood sampling, particularly in synchronising the medication administration time with sampling. Pharmacists were in the lead position to monitor the appropriateness and ensure sustainable improvement.

This project was limited by the inclusion of only two TDM analytes of Gentamicin and Vancomycin. Comparatively, other studies covered other analytes including anti-epileptics, Cyclosporine and Digoxin (4-5). Thus, our project could have underestimated or overestimated the inappropriateness.

## Conclusion and the Next Steps

The reduction in the percentage of inappropriate TDM sampling was contributed by the introduction of multiple measures including an educational program and sampling reminder system. This project has proven to be sustainable since its commencement in 2015 until 2019, with the reduction of percentage of TDM sampling inappropriateness to lower than the target of 20%. To ensure sustainability of the project, our team appointed our TDM pharmacist as the head of project to ensure project continuation, regular audit management,

and to teach. The digital reminder system can be implemented at facilities equipped with similar computerised physician order system.

## Acknowledgements

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## Conflict of Interest

None

## Funding

None

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# INCREASING THE PERCENTAGE OF BEDSIDE DISPENSING IN ADULT MEDICAL WARDS OF HOSPITAL SULTANAH NUR ZAHIRAH, KUALA TERENGGANU

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## Abstract

Bedside dispensing (BD) is one of the clinical services offered by the Pharmacy Department to patients prior to their hospital discharge. Increment in number of BD may improve the patients' discharge process, patients' satisfaction and their medication knowledge. This project aimed at increasing the percentage of BD in adult medical wards of Hospital Sultanah Nur Zahirah (HSNZ). The proposed standard of BD percentage was at least 30% within four months of intervention. The project was conducted from November 2016 to December 2019. The monthly report of pharmacy BD record was analysed to assess the achievement of BD. A pre-interventional retrospective BD data review of discharge prescriptions received throughout 2016 showed that only 8.1% of discharge prescriptions were dispensed at the bedside. A closed-ended questionnaire to evaluate knowledge, experience and perceived contributing factors to the low percentage of BD was distributed to nurses, inpatient pharmacists and ward pharmacists. The main contributing factors identified included time constraint, poor understanding of BD workflow, inadequate staff awareness and lack of cooperation among healthcare providers. Institutional BD workflow was implemented involving the introduction of discharge prescriptions pick-up points at medical wards, and a scheduled timing for prescriptions collection and dispensing during office hours. Three face-to-face educational sessions on overview of BD and its latest workflow were given to staff nurses, inpatient pharmacists at discharge pharmacy unit and ward pharmacists. In 2017, the percentage of BD increased from 8.1% to 28.0% after the implementation of interventions, and subsequently to 60.0% in the latest maintenance phase of January until December 2019. The sustainable implementation of this BD program could be shared and implemented at other facilities with inpatient discharge services to improve healthcare delivery.

**KEYWORDS:** Bedside dispensing, pharmacist, transition-of-care, meds-to-beds.

## Problem

Bedside dispensing (BD) program involves hand-delivering of discharge medications to hospital patients' bedsides by pharmacists (1). This includes counselling on devices and medications that come with special instructions, identification of potential barriers to compliance and finding solutions accordingly (1). Low implementation of BD may lead to ineffective patient care in medication information delivery, delay in patients discharge, reduce patients' satisfaction, polypharmacy and medication wastage. According to the Pharmacy Management Report (PF) 2016 by the Ministry of Health (MOH), only 26.1% of discharge prescriptions were dispensed at the bedside in MOH government hospitals. Terengganu ranked the fourth lowest state, with a mere 11.8% achievement (2). Hospital-wide execution of BD in Hospital Sultanah Nur Zahirah (HSNZ) was the least, at only 5%, followed by Hospital Besut (16.6%) and Hospital Hulu Terengganu (18.8%) (2).

According to the Guidelines by MOH for Inpatient Pharmacy Practice, BD is encouraged to be practiced as an alternative to traditional medication dispensing at pharmacy counters (2). In the Pharmacy Practice and Development Action Plan 2018, MOH set the BD target at 20-25% for main hospitals (including HSNZ), 40-50% for major hospitals with specialists and 70-80% for hospitals without specialists (3). BD priorities are given to patients discharged with devices such as inhalers and insulin pens, newly diagnosed chronic diseases patients, patients who are on many medications, patients on narrow therapeutic index medications and patients who have poor understanding and knowledge on medications usage (1). The re-use of patient's own drugs (PODs) for discharge following medications reconciliation by ward pharmacists is encouraged to prevent wastage and polypharmacy (1).

Pharmacy is one of the critical clinical support units in HSNZ, a state general hospital, situated in the Kuala Terengganu district with a population of 343,284. HSNZ serves as a reference hospital for district hospitals and health clinics throughout Terengganu state, with a population of 1,250,000.

HSNZ is equipped with 43 wards, and 1,107 beds involving 12 adult medical wards, including two intensive care units with a total of 240 beds. Bed occupancy rate (BOR) in adult medical wards is relatively high, ranging from 53.0 to 103.4%, compared to other wards which has a BOR between 24.2 to 90.6%. Our discharge pharmacy unit receives an average of 470 discharge prescriptions per month from 10 non-intensive care adult medical wards. Patients in these wards often have multiple comorbidities requiring various medications that may come with confusing instructions. Therefore, these patients may benefit substantially from a patient-centered counselling in BD program. Ten ward pharmacists were responsible to conduct the BD program at 10 non-intensive care adult medical wards. Upon identification of patients who were fit for discharge and medications prescribed by medical doctors, ward pharmacist would acquire the discharge prescriptions to have them dispensed at the bedside. These prescriptions would be processed and prepared at the discharge pharmacy unit prior to BD by ward pharmacist. Throughout 2016, our Pharmacy Department received 5,817 discharge prescriptions from 10 adult medical wards, but only 471 (8.1%) of them were able to be dispensed at the bedside. This project aimed to increase the percentage of BD in non-intensive care adult medical wards of HSNZ to a minimum of at least 30% within four months of intervention.

## Background

BD program allows pharmacists to explain in detail about the discharge medications, especially to patients who need specific medication instructions, to optimise medication benefits and to prevent medication errors (4). The management of chronic conditions with multiple medication has called for careful monitoring of adverse effects and drug interactions where clinical pharmacists can play their significant roles

in care transition programs, including BD (5–7).

Transition-of-care service of BD is offered to enhance the patient's discharge process. By having pharmacists deliver discharge medications to the patients before leaving the hospital, the program eliminates the need to stop at the discharge pharmacy unit during the discharge process (4).

In Serdang Hospital, a cross-sectional study in 2013 found that despite having 56.0% of inpatients discharged during office hours, the percentage of BD performed by pharmacists was only 13.0% (8). The main causative factors were imbalanced workforce allocation among inpatient pharmacy units, limited space for storage of prepared BD medications at the satellite pharmacies and suboptimal implementation of BD sessions scheduled twice daily (8). Centralisation of discharged medication preparation at a single discharge pharmacy unit, assignment of a pharmacist to monitor BD activities, and increasing the scheduled BD sessions from two to four sessions per day improved the percentage of BD from 13.0% to 64.5% in 2015 (8). In the National Health Service of United Kingdom, interviewing patients regarding PODs during medication reconciliation and preparation of medication a day before the discharge helped increase percentage of patients being discharged before 12 noon, reduced medication error and patients' waiting time (9).

Effective and sufficient human resources were critical to ensure good implementation of BD program. Addition of a transition-of-care pharmacist played a significant role in aiding delivery of BD service. Compared to the control year, there was a significantly lower medication related re-admission rate per month during the transition-of-care pharmacist's involvement in an academic medical center in Southern Arizona (i.e. median rates of 25 vs 27.5) (10). The pharmacist coordinated patient discharge, attended inter-disciplinary discharge coordination meetings, ensured appropriate discharge orders, facilitated the medications preparation and educated patients on discharge medications (10).

The impact of BD program can also be elevated through inter-disciplinary collaboration. Participation in a BD program with a prior inter-disciplinary team rounding in an acute care teaching hospital in California was found to be associated with significant decrease in odds of a 30-day re-admission (OR, 0.50; 95% CI, 0.90-0.84) (11). The inter-disciplinary team rounding helped to better coordinate hospital discharge and communication between different departments including discharge planning, social workers, medical doctors, physical therapists, nursing and pharmacy units (11).

## Measurement

The primary outcome of the study was to improve the percentage of BD provided in adult medical wards. It was calculated as the number of prescriptions dispensed at the bedside over the total number of discharge prescriptions received during office hours. Prescriptions received during weekends, public holidays and after operating hours on weekdays were excluded due to there being no on-call pharmacist for BD. Patients with impaired memory, cognitive or conscious level such as post-stroke or demented geriatric patients would have their medications dispensed at the bedside to their caregivers.

The BD numbers were irrespective of the number of discharge medication dispensed per prescriptions. For example, if one discharge prescription consisted of five different medications and they were all dispensed at the bedside, the quantity counted for BD would be one. Data of BD was collected on a daily basis by adult medical ward pharmacists through Clinical Pharmacy Report Form (CP3). Total number of discharge prescriptions received within office hours from medical wards was collected from the Statistics of Discharge Prescriptions Workload at discharge pharmacy unit. A pre-intervention study showed only 8.1% of discharge prescriptions were dispensed at the bedside throughout 2016. Based on human resources availability and pre-intervention achievement factors, the project team proposed a standard of a minimum of 30% of discharge prescriptions from adult

medical wards being dispensed at the bedside. This standard was implemented in HSNZ prior to the introduction of MOH target in 2018 which was 20-25% for main hospitals.

## Initial Assessment of the Problem

A problem analysis chart was developed to analyse the possible contributing factors to the problem (Figure 1). According to the analysis, a few factors contributing to the problem included lack of collaboration between healthcare providers, inadequate awareness among hospital staff, poor BD workflow understanding and time constraint to execute BD. A questionnaire consisting of 10 closed-ended questions were distributed to a total of 41 staff, comprising of ward nurses, inpatient pharmacists and ward pharmacists. This questionnaire assessed staffs' awareness on the BD workflow, perception on inter-disciplinary collaboration for implementation of BD, and main challenges of BD. This survey was conducted before and after intervention, and was implemented to evaluate effectiveness of the intervention.

More than a third of the respondents (39.0%; n=16) were unclear on how BD should be performed. This was caused by the absence of institutional BD workflow prior to the intervention phase. Only 24.4% (n=10) agreed that BD program required inter-professional collaboration between medical doctors, pharmacists and staff nurses. Heavy workload (21.9%; n=9), time constraint (19.5%; n=8) and lack of educational sessions on BD program (17.1%; n=7) were perceived as the key barriers to executing BD.

Our discharge pharmacy unit caters for preparation and counter dispensing for various ward departments in HSNZ. Thus, to better understand the time constraint factor to execute BD, we conducted a retrospective review of discharge prescriptions of multiple ward departments at our discharge pharmacy unit according to receipt timing, between November until December 2016. Out of 4,498 prescriptions, 75.0% (n=3,374) were received after 12 noon, causing planned BD program in adult medical wards difficult to be conducted due to patient congestion at the discharge pharmacy unit, especially towards the end of office hours. Discharge prescriptions for BD were also picked up by ward pharmacists either at patients' beds or ward counters with no specific timing for prescription collection and BD. Our ward pharmacists were also responsible for other tasks including medication history assessment, case clerking, bedside counseling, therapeutic drug monitoring and ward rounds involvement with the medical team.

## Strategy

Three interventions were implemented from January until April 2017. Firstly, we devised a BD institutional workflow to support effective planning of the program. The workflow included an addition of two critical steps for BD program (Figure 2). The staff responsible for each step were also included in the workflow to ensure staff awareness on responsibility in each step of BD implementation and to promote staff communication. A specific discharge prescription pick-up point at 10 adult medical wards was also introduced by placing BD Pick-up Boxes in each ward. A scheduled timing for prescription collection (at 11 a.m.) and dispensing (at 12 p.m.) during office hours was set to avoid delay in completing office-hour discharge prescriptions.

Secondly, three face-to-face 30-minute educational sessions were given to ward nurses, inpatient pharmacists and ward pharmacists. A session was conducted among 27 ward nurses who were mostly nurse supervisors (Sisters) and represented the adult medical wards. Four inpatient pharmacists and ten participating adult medical ward pharmacists also received the educational session, contributing to 100% coverage for pharmacy-related staff. These sessions emphasised on the introduction of BD, its benefits and latest workflow of implementation, and received encouraging feedback from the audience, especially in terms of understanding the latest workflow.

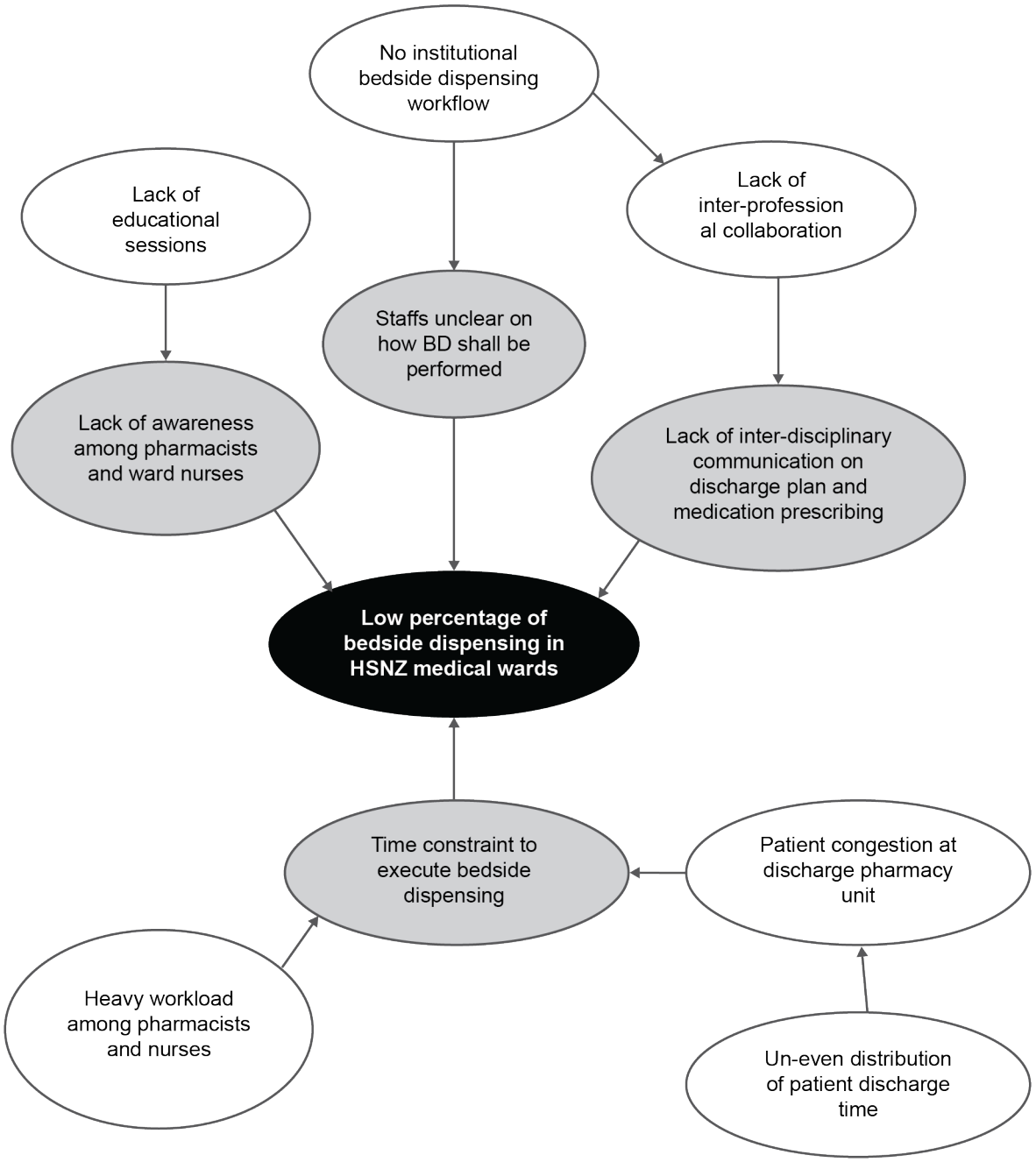


**Figure 1.** Problem analysis chart of low percentage of bedside dispensing in medical wards of HSNZ

Thirdly, the contributing factors of heavy workload and time constraint were addressed through initiatives by human resources. One of our pharmacists at the discharge pharmacy unit was assigned with a BD role. The BD pharmacist was responsible in assisting the adult medical ward pharmacists in handling discharge orders, medication filling and educating patients on discharge medications during their leave. The Ward Pharmacy team highly welcomed this intervention as it helped improve the quality of discharge medication dispensing.

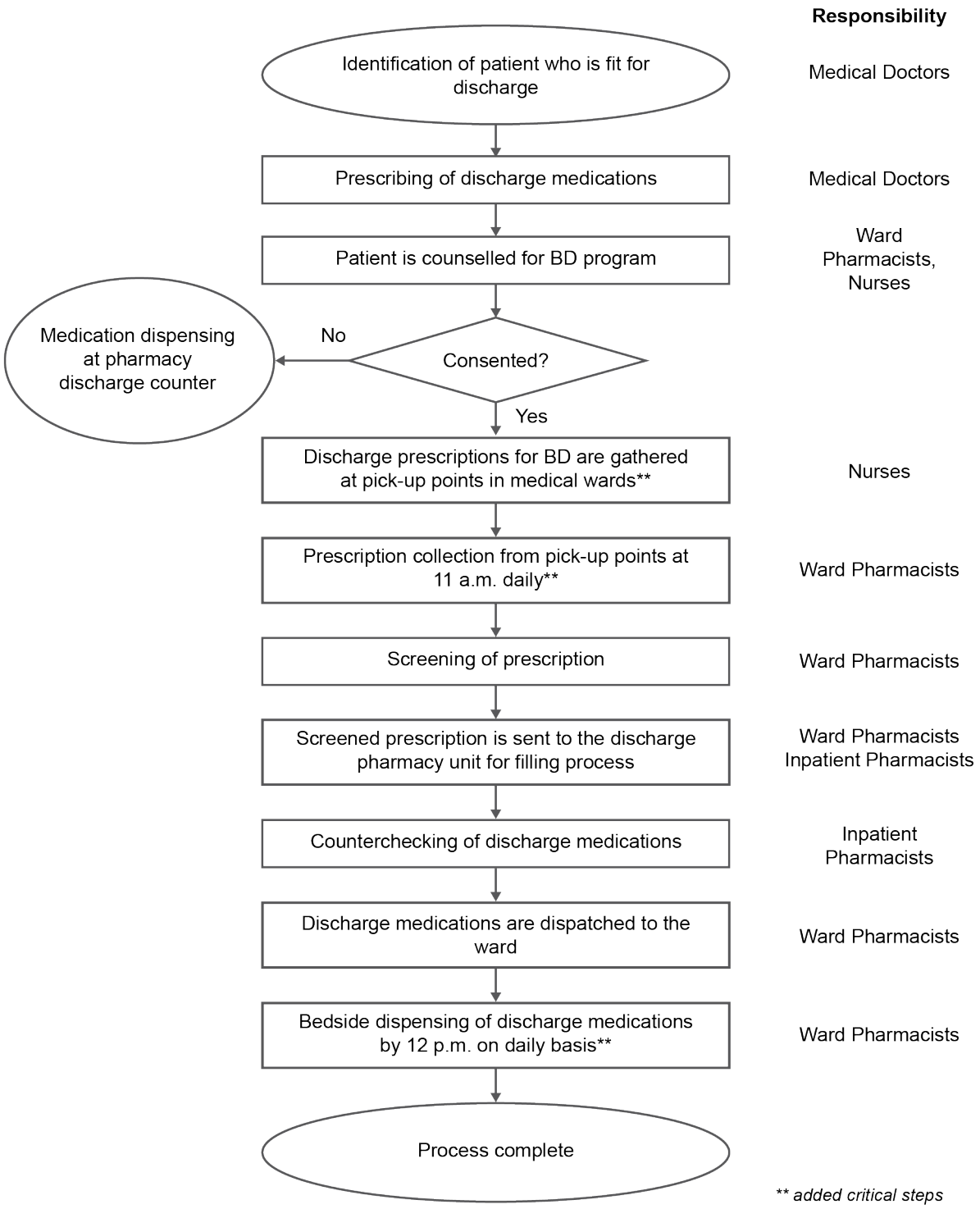


**Figure 2.** Institutional workflow to increase percentage of BD.

## Results

Implementation of each subsequent intervention had a significant effect on the increment of BD percentage. Our main outcome measure was the percentage of BD for discharge prescriptions received from adult medical wards from May 2017 until December 2019.

During the first cycle post-intervention (May until December 2017), the percentage of BD increased to 28.0% (n=1259) out of the total 4,491 discharge prescriptions (Figure 3). The post-interventional monitoring continued until December 2019. BD percentage improved and remained above the standard of 30%, with the latest achievement in the 12-month duration of 2019 showing 60.0% (Figure 3). The level of staff awareness on BD workflow improved after the interventions were implemented. Staffs were requested to answer questionnaire on BD before and after each educational session. Percentage of staff who were clear on how BD should be performed increased from 61.0% (n=25) to 100% (n=41). All of the staff (100%, n=41) also agreed that BD program required inter-professional collaboration, especially with the implementation of institutional BD workflow.

## Lessons and Limitations

This study delved in depth into the problem of low BD percentage in our medical wards, its main contributing factors and possible solutions.

Incorporating innovative interventions into the process workflow such as setting up discharge prescription pick-up points and having a scheduled timing for prescription pick-up and dispensing were effective in improving the previous process workflow.

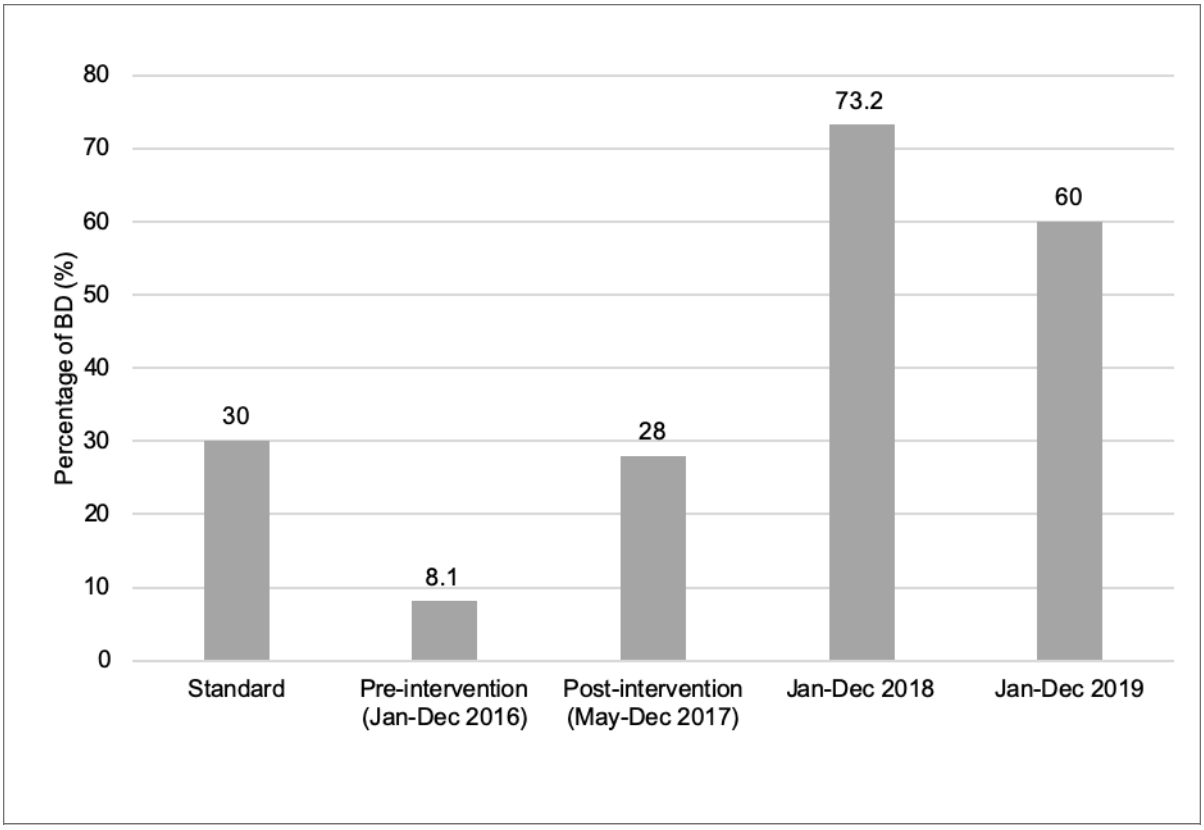


**Figure 3.** Percentage of BD in adult medical wards (n=10 wards) of HSNZ from January 2016 until December 2019.

Multiple benefits were gained, including less travelling of patients between wards and discharge pharmacy unit, reduction of workload to ward pharmacists and better time management among staff. This project also highlighted the importance of staff adherence to the improvised workflow process for BD to achieve its optimal effect.

The group consensus of our study standard in 2016 was made prior to the MOH target, which was only released in 2018. This explained the dissimilarity between our QA standard (30%) and the MOH target (20-25% for main hospitals).

## Conclusion and the Next Steps

This study explored multiple contributing factors that caused a low percentage of BD. Interventions were planned and conducted to tackle each factor. These included discharge prescription pick-up points, scheduled timing of dispensing, educational sessions and appointment of inpatient pharmacist devoted to BD. Although we were unable to achieve the QA standard of BD percentage during the first cycle of post-interventional period, a sustainable continuous improvement enabled achievement of the target in the subsequent cycles. Nonetheless, we managed to surpass the MOH target of at least 20% since the early interventions were already in place.

The project team appointed an inpatient pharmacist in discharge pharmacy unit as the champion for regular audit management and promotion of BD to sustain this improvement. The workflow will also be internalised into the institutional inpatient pharmacy standard operating procedure. Subsequently, our team plans to expand educational interventions to the medical doctors. The outcome assessment in terms of patients' satisfaction, waiting time at discharge pharmacy unit, medication understanding, compliance level and medication-related re-admission rates will be evaluated in the future to determine the patient-specific outcome of BD program. The improvement strategies in this study can be shared and implemented at other facilities with inpatient discharge service to improve the efficiency of healthcare delivery.

## Acknowledgements

We wish to thank the Director General of Health Malaysia for his approval to publish this work. We are grateful to the State Health Director and the Deputy State Health Director (Pharmacy) of Terengganu for their support towards this project. We would also like to express our gratitude and appreciation to the Director of HSNZ, Chief Pharmacist, all medical doctors, pharmacists and staff nurses for their assistance and involvement throughout the project.

## Conflict of Interest

None.

## Funding

None.

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# INCREASING PERCENTAGE OF PRESCHOOL CHILDREN RECEIVING DENTAL TREATMENT AT KINDERGARTENS IN MACHANG DISTRICT

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## Abstract

Preschool children are one of the major target groups of the Oral Health Program, Ministry of Health Malaysia. However, caries prevalence of preschool children due to unmet treatment needs remains high. Thus, it is imperative for preschool children to receive dental treatment to maintain or restore function and aesthetics, prevent premature tooth loss and improve their quality of life. We aimed to increase the percentage of preschool children receiving dental treatment at kindergartens from 9.8% to 30% in a year. A cross-sectional study was conducted in January 2015 to March 2015 to identify factors contributing to low percentage of preschool children receiving dental treatment using a structured questionnaire modified and adapted from literatures. Ten kindergartens in Machang District were randomly selected, and a total of 200 preschool children, 180 parents and 13 dental therapists in Machang District were recruited for this study. Remedial measures were implemented in April 2015 until September 2015, followed by a post-remedial evaluation in October 2015 to December 2019. The factors contributing to low percentage included inconvenient visit schedule, lack of monitoring system, preschool children at kindergartens refusing dental treatment, and lack of oral health knowledge and awareness among parents. A series of interventions were introduced including improvement of care process, systematic planned visits, and formation of a dedicated team for kindergartens. Oral Health Education and seminars were given to parents. Supportive environment and innovations were created, including colorful attire, cartoon accessories and Benzo Kids' eye-wear tools. The Benzo Kids functioned as a smart phone holder for a child to watch their favourite video during treatment to divert the child's attention and reduce anxiety. The percentage of preschool children receiving dental treatment at kindergartens increased from 9.8% (2014) to 55.9% (2019), which exceeded the initial target of 30%. This study has had a significant impact on the number of deciduous teeth with dental caries of these preschool children when they progress to primary one. The HMIS data showed a decreasing trend of dental caries per 100 children from 80(2013) to 58(2019).

**KEYWORDS:** Preschool children, dental treatment, kindergarten, quality improvement study

## Problem

In Malaysia, 86% of rural and 69% of urban preschool children have experienced dental caries, most of which remained untreated (1). With only 12.9 % of 5 years-old being caries-free (1995), Malaysia lags behind the Oral Health Goal for the year 2020 set by the World Health Organization (WHO) to have 50% caries-free children (5-6 years-old). According to WHO, 60% to 90% of school children worldwide have experienced dental caries (2). Local data based on Health Management Information System (HMIS) report in 2014 of Machang dental clinic showed that only 9.8% of preschool children received dental treatment at kindergarten, not achieving the District Specific Approach (DSA) standard of 30%. Therefore, it is imperative that this problem is addressed to ensure pre-school children receive dental treatment to preserve or restore function and aesthetics, prevent early loss of teeth, and improve their quality of life.

Machang District Dental Health Clinic is located at Machang's city centre close to the Machang District Hospital. Machang District consists of 79 kindergartens with 2289 preschool children. Machang District Dental Health Clinic provides dental services to several target groups including toddlers, preschool children, primary school students, secondary school students, antenatal mothers, adults, special needs children and senior citizens.

Patients are seen at dental outpatient clinics, schools, hospitals and during domiciliary visits. The dental mobile team consists of dentists and dental therapists who visit elderly patients in elderly centers, and patient's home at least once a year. Secondary school children (13 to 17-year-olds) are seen and treated by dentists. Preschool children (5 to 6-year-olds) and primary schoolchildren (6 to 12-year-olds) are treated by trained dental auxiliary, dental therapists. The dental therapist will conduct dental visits and provide dental treatment to preschool children at least once a year. The services include promotive, preventive and curative activities towards the control of oral diseases. Priority is given to government-aided kindergartens and are extended to private kindergartens.

Children under the age of six generally spend most of their time with parents and teachers who play a central role in educating and encouraging children to have a healthy oral condition. Preschool children's oral healthcare is influenced by their parent's knowledge, attitude and practices. Dental anxiety and fear of dental treatment among preschool children may contribute to the problem. Inconvenient schedule arrangement among dental team was among the factors that contributed to the problem of giving dental treatment to preschool children at kindergarten. The processes and schedule could be improved for the benefit of preschool children. To understand the current problem, possible contributing factors and designate institute appropriate strategies for improvement, we conducted a quality improvement study aimed to increase the percentage of preschool children receiving dental treatment at kindergartens in Machang District from 9.8% to 30% within a year.

## Background

A study in Beijing, China reported that 648 (45.5%) preschool children in kindergarten had utilised oral health services in the past 12 months, while 24.3% had received preventive oral health services or dental treatment. Routine check-ups and receiving preventive measures accounted for 63.2% of the children who utilised oral health services in the past 12 months (3). This regional study showed that 12.3% to 42.3% preschool children had accessed oral health services within the past 12 months (3). However, several barriers impeded children from receiving timely dental treatment; the most frequently cited being insurance related problems for children and adults. Other barriers included limited dental services for children aged 2 years, perceived poor quality of some dental practices, lack of emphasis on prevention-based dental care, poor care-coordination, and insufficient culturally-appropriate care. Important family-level barriers included

parental oral health literacy, cultural factors, limited English proficiency and competing priorities. Several solutions were proposed to address these modifiable factors through strategic oral health policies, community outreach and improved care coordination between physicians, dentists and early childhood care providers (4).

Many studies reported that health-related behaviors are established in preschool children during the period of primary socialisation (1). Good management of preschool children is essential. This leads to a motivated patient, happy to undergo any necessary treatment, instills confidence and improves attitude to oral health of other family members. Rayner (5) showed that the combination of tooth brushing in school and dental education among parents improved the oral hygiene of their children. Cohen (6) suggested that it is important to advice the parents and children in the same environment. More emphasis should be placed on teaching proper tooth brushing skills and on positive parental engagement. Good teamwork between dentists, teachers and parents, and using good pedagogical approach for effective preventive and oral healthcare treatment for preschool children are important (6).

## Measurement

The initial data was gathered using the Health Management Information System (HMIS), questionnaire and checklist survey. Data from HMIS was used to calculate the percentage of preschool children receiving dental treatment in kindergarten. Preschool children are categorised as children aged 5 to 6 years old, and kindergarten is a school or class for these children. Dental treatment is any variety of treatment of the teeth and adjacent tissue to restore or maintain oral health and function. The indicator of this study was the percentage of preschool children receiving dental treatment at kindergarten using the formula below:

$$= \frac{\text{Number of preschool children receiving dental treatment at kindergarten}}{\text{Total enrolment of preschool children at kindergarten in Machang district}} \times 100\%$$

The target of this indicator was discussed at the state level and determined to be more than 30%. Data was collected on a monthly basis and the achievement was calculated every six months. The HMIS data in 2014 showed our achievement was only 9.8%. Our baseline findings from January to March 2015 revealed that only 2.2% preschool children received dental treatment in their kindergarten in Machang District. The implementation of strategies for change started from April until September 2015, and re-evaluation of the effectiveness was conducted by our team members every three months for five cycles until December 2019.

## Initial Assessment of the Problem

The existing process of care was reviewed, and a few critical steps were identified and added to emphasise on the implementation of a second visit for dental treatment if needed, and referred to the nearest dental clinic if further treatment was required (Table 1). The process of care started with the preparation of scheduled visits to all identified kindergartens by dental therapists. During the first visit, Dental Health Education (DHE) was given to 90% of parents and caregivers in attendance, and all teachers. Tooth Brushing Drill (TBD) was conducted among all kindergarten students. Then, the dental checkup or screening was performed by a dental therapist. The oral health status of the kindergarten students was informed to the parents. For students who needed treatment, consent was obtained from the parents. The kindergarten's students with dental problems were treated during the second visit.

A cross-sectional study was conducted to identify factors contributing to the low percentage of preschool children receiving dental treatment. Ten kindergartens were randomly selected from 79 kindergartens with a total enrolment of 2224 children at Machang district. The calculated sample size was 213 with the following parameters: proportion 0.7, significant level (α) of 0.05, precision (Δ)

of 0.065 and dropout rate of 20% (7). The consent form was distributed to all parents prior to the study. All kindergarten students (n=200), aged 5 to 6 years old from the 10 kindergartens were recruited for this study. Inclusion criteria were children aged between 5 to 6 years old with parent's or caregiver's consent. Data was obtained using a structured questionnaire modified and adapted from Alsarheed (7) to assess attitude of children towards dental therapists and towards dental treatment. This was an assisted questionnaire with photos delivered by an officer to a small group of three children (7). For evaluation of anxiety, Norman Corah's Dental Anxiety Scale 1978 was adapted, using images of dental treatment which were presented to each child. The child then chose a face emoticon (happy face, natural face and sad face) to represent their response (8). To determine oral health knowledge, attitude and practice (KAP), a self-administered questionnaire by Singhal et al., (9) was adapted and translated into simple Malay language and administered to 180 parents or caregivers at the same 10 kindergartens. The questionnaire consisted of three sections with each section covering a specific domain. Each section has five questions and covered oral health knowledge, attitude and practices. A score of one reflected a correct answer and a score of zero indicated an incorrect response. An overall oral health knowledge and attitude score was calculated by adding each correct answer for all questions for each participant and converted into percentage.

The level of oral health KAP was determined using Bloom's cut-off points - good (80-100%), moderate (60-79%) and poor (0-59%) (9). In addition to that, a checklist survey was performed among all dental therapists in Machang District consisting of questions related to the scheduled visit to kindergartens and annual leave to determine problems encountered in delivering dental treatment to preschool children. The data of preschool children's oral health status was extracted from the HMIS report.

Three quarters of kindergartens students (n=150, 75%) were uncooperative towards dental treatment. Their cited reasons were anxiety (74%) and fear (26%). Most of them were anxious about dental treatment due to dental instruments (85%) and dental therapists (15%), (Figure 1). Nearly two-thirds of parents or caregivers (60%) lacked knowledge on their children's oral health. Only 22% of them had good attitude towards their children's oral health. The oral health practices of parents or caregivers towards their children is demonstrated in Table 2. Most parents or caregivers reported moderate oral health practices for Questions 1 and 2. However, most parents or caregivers showed poor oral health practices for Question 4; 91.6% parents took their child to visit the dentist only when needed and Question 5; 81.7% parents visited the dentist only when their child experienced pain. Out of 13 dental therapists in Machang District, more than half of them reported having problems with arranging scheduled visits, some cited lack of monitoring system, while others reported annual or emergency leave.

Therefore, inappropriate visit schedule to kindergartens, lack of monitoring system, preschool children refusing dental treatment due to anxiety, and lack of knowledge and awareness among parents were the major factors contributing towards the low percentage of preschool children receiving dental treatment in Machang District.

**Table 1:** Model of Good Care on dental treatment among preschool children at kindergarten.

| Critical Step | Criteria | Standard | Pre-remedial | PDSA Cycle 1 | PDSA Cycle 2 |
|---|---|---|---|---|---|
| Oral health screening by dental therapist (First visit) | - Do dental check up to all kindergarten's children<br>- Identify the children with dental problems and treatment needed<br>- Dental health education (DHE)<br>- Tooth brushing drill (TBD) | 100% | 100% | 100% | 100% |
| Inform parent of oral health status and to obtain treatment | Obtain consent from parents for dental treatment | 100% | 85% | 100% | 100% |
| Implement second visit | - Dental health education (DHE)<br>- Tooth brushing drill (TBD)<br>- Role play/ control oral disease<br>- Do the dental treatment if needed and refer to the nearest dental clinic if further treatment required | 100% | 75% | 85% | 100% |
| Patient referral | Refer patient to the nearest dental clinic if treatment needed | 100% | 100% | 100% | 100% |
| Data collection | - HMIS: Reten PG307, PG201, PG203<br>- Update checklist for coverage of kindergartens<br>- Record HMIS Reten form | 100% | 100% | 100% | 100% |

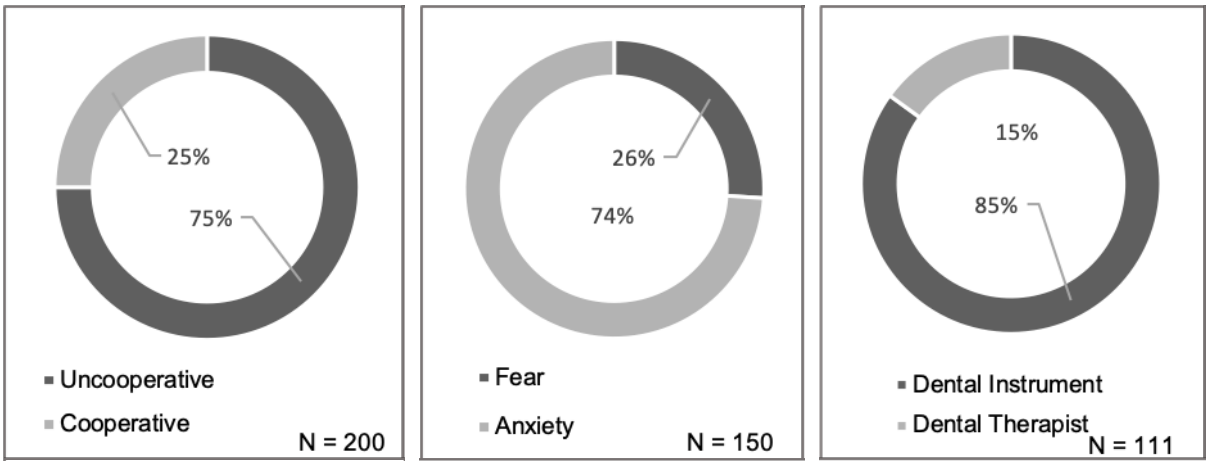


**Figure 1:** Attitude and anxiety among preschool children towards dental treatment.

**Table 2:** KAP among parents and caregivers towards oral healthcare (N=180)

| Scoring | Frequency of Responses (Percentage) | | |
|---|---|---|---|
| KNOWLEDGE: | | | |
| Good (80-100%) | 45 (25%) | | |
| Moderate (60-79%) | 27 (15%) | | |
| Poor (0-59%) | 108 (60%) | | |
| ATTITUDE: | | | |
| Good (80-100%) | 40 (22%) | | |
| Moderate (60-79%) | 36 (20%) | | |
| Poor (0-59%) | 104 (58%) | | |
| PRACTICE: (Question) | | | |
| 1. How often do you clean your child's teeth? | Once a day 9.4% | Twice a day 85% | Never 5.6% |
| 2. How frequently do you change your child's toothbrush? | 3 monthly 5.6% | 6 monthly 72% | Once a year 22% |
| 3. How long do you take to brush your child's teeth? | 1 minute 88.9% | 2 minutes 11.1% | 3 minutes 0% |
| 4. How frequently do you take your child to the dentist? | Once a year 5.6% | Twice a year 2.8% | When needed 91.6% |
| 5. At what age should you take your child for his/her first dental visit? | 7 years old 11.1% | 1 year old 7.2% | When felt pain 81.7% |

## Strategy

Our SMART (specific, measurable, achievable, realistic, and timely) aim was to increase the percentage of preschool children receiving dental treatment by dental therapist in kindergartens so that 30% of children can be treated during the visit. We performed four PDSA (plan, do, study, act) test cycles.

PDSA cycle 1: Our initial intervention was to establish a supportive and friendly environment during treatment such as donning colorful attire and mask, and modifying dental instruments by placing cartoon accessories at the end of hand instruments to help children overcome anxiety. The lack of oral health knowledge, attitude and practices among parents improved through oral health education and motivation by dental officer that was offered once a year. Seminar and talks on oral health care and demonstration of dental treatment such as fluoride varnish, dental material exhibition and question and answer sessions were conducted by dental officers and dental specialists. Based on feedback received, this strategy might be sustainable as it took place only once a year and involved only a minimal cost because the budget was supported by the kindergartens' administrators.

Improving the care process by introducing a third time dental visit to certain kindergartens was implemented to increase the coverage of dental treatment. Two visits were usually scheduled at intervals of one week with the first visit for dental checkup and tooth brushing drill, and the second visit for simple treatments like fluoride varnish. The team took the initiative of arranging a third visit for a particular kindergarten when they were scheduled to visit a primary school in close proximity to the kindergarten. The third visit was for the team to provide fluoride varnish to children who could not be treated during the second visit. The third visit successfully increased the number of children receiving dental treatment to 16.5%. However, children who needed treatment like filling and scaling could not be treated at their kindergartens due to logistics and facility reasons.

PDSA cycle 2: To overcome the issue of children who required scaling and filling, the third visit was strengthened. Planned visits to kindergartens were rescheduled according to topography and distance of kindergartens to the nearest primary school, and kindergartens remained open throughout the year. Children who needed such treatment would be brought to the nearest primary school with their parents' consent. Children would be accompanied by their teachers during the treatment at the primary school. The dental treatments increased to 19%. However, based on feedback from the dental therapists, the strategy was quite risky as teachers needed to accompany children from kindergarten to the primary school.

PDSA cycle 3: We hypothesised that our intervention may be more effective if it were more organised, systematic and could be monitored better. To achieve this, a Dental Officer in Charge (DOIC) was assigned and a dedicated team for pre-school care was formed, consisting of a dental therapist and a dental officer for each team. Monitoring was done every three months. This led to dental treatments increasing to 36%. This strategy received positive feedback; indicating that it might be sustainable due to good communication and team work between the dental therapists and dental officers.

PDSA cycle 4: For our final test cycle, an innovation called 'Benzo Kids' was developed to divert children's attention and reduce anxiety during treatment. By implementing Benzo Kids, the percentage of preschool children receiving dental treatment increased to 43%.

## Results

The number of uncooperative children towards dental treatment decreased from 150 in 2014 to 60 in 2019.

Children's attitude towards dental treatment showed an improvement as the number of children with anxiety decreased from 95 to 30 children. Levels of knowledge, attitude and practices among parents and caregivers towards children oral health care improved. All parents consented to their children's dental treatment and was aware of the dental treatment being delivered at kindergartens. All dental therapists followed new scheduled visits to kindergartens with the dedicated team.

The percentage of pre-school children receiving dental treatment at kindergartens increased from 9.8% (2014) to 70.3% (2019) (Figure 2). The initial target set was 30% in 2014. Even though we cannot achieve our objective in the stipulated time frame, improvement was seen following each PDSA cycle (Figure 2). The District Dental Officer (DDA) increased the standard to more than 50% in 2018. The ABNA was reduced from 20.2% to 0% following continuous remedial actions and strategies taken from PDSA cycle 1 to PDSA cycle 4. This study led to a significant impact on the number of deciduous teeth with dental caries of these pre-school children when they progress to primary one. The HMIS data showed that the number of dental caries per 100 children decreased from 80 (2013) to 58 (2019).

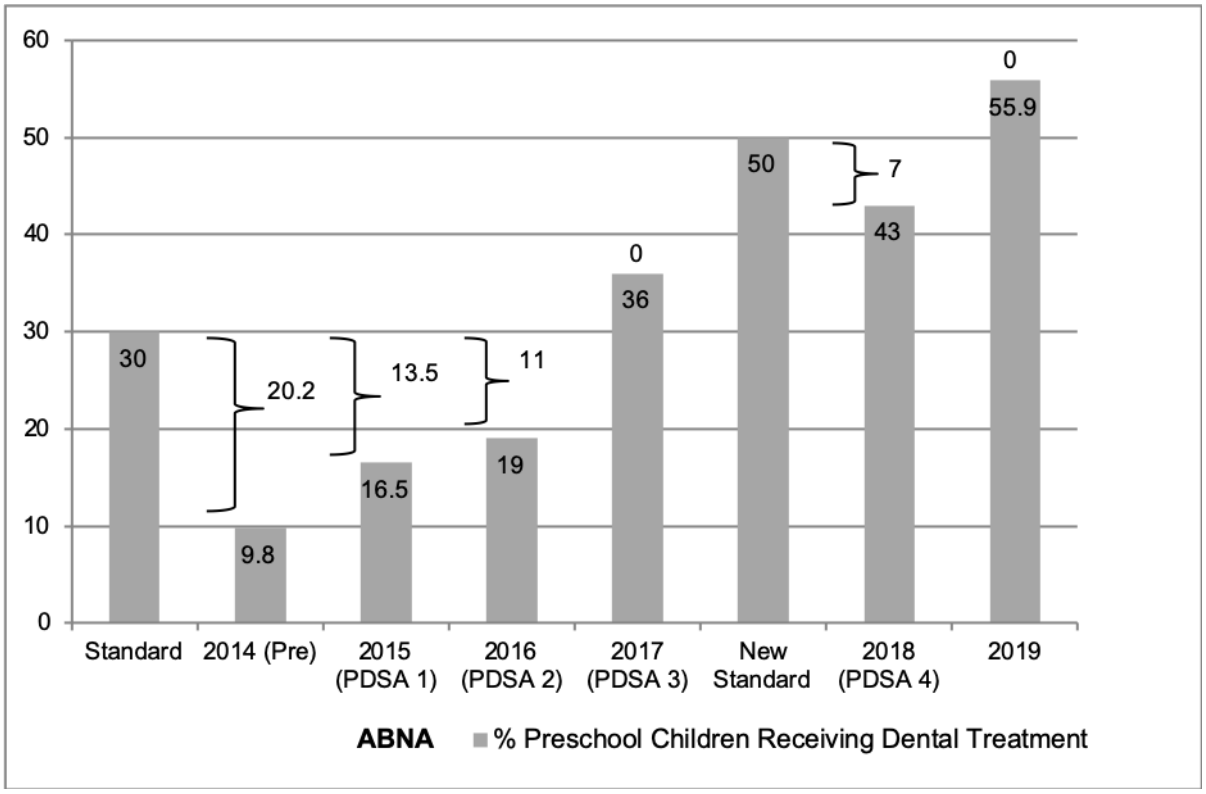


**Figure 2:** Pre and post-remedial achievements: percentage of preschool children receiving dental treatment at kindergartens in Machang District.

## Lessons and Limitations

This project aimed to increase the percentage of dental treatment among pre-school children in kindergartens by dental therapists and dental officers. This study also focused on implementing a sustainable solution rather than a short-term intervention.

A key lesson learnt during this process was the importance of PDSA cycles, which helped ensure that at each stage, the intervention method was optimised before being fully implemented across the district. Our findings suggest that each intervention was effective. The formation of a dedicated team had a positive impact, proved to be the most effective intervention, and had a greater chance of being sustainable. In comparison, the intervention that was least effective was introducing a third dental visit to the kindergarten, which added workload to the dental therapists. We were able to achieve our target of more than 50% preschool children receiving dental treatment at kindergartens in 2019. Good teamwork and communication between kindergarten's teacher and dental staff was one of the main factors lead to the project successful.

There were also minor issues regarding the cost of supplying and distributing colorful masks, gowns, cartoon accessories and 'Benzo Kids'. For our intervention to succeed, we had to ensure that these modified gowns, masks and cartoon accessories were distributed to all dental therapists, which was not feasible due to a lack of budget. However, this strategy may be possible in the future if there is an increase in financial resources.

## Conclusion and the Next Steps

The project team was able to identify the factors that contributed to the low percentage of pre-school children receiving dental treatment at kindergartens. The team also developed interventions that addressed these problems to increase the percentage of dental treatment performed. Continuous monitoring of remedial measures is necessary to ensure achievement of the DSA standard. To ensure continuous improvement, the team implemented 'Little Precious Child Oral Care' programme in all kindergartens. By making all kindergartens at Machang district as a 'Tadika Angkat' (adopted kindergarten), we would be able to improve the oral health status of all kindergarten children.

Due to the significant results of this project, it is necessary to ensure these improvement methods and interventions are shared throughout the state.

## Acknowledgements

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## Conflict of Interest

None.

## Funding

None.

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# Quality Improvement Report (QIR) for Q Bulletin Guideline for Authors

This guideline is the modified version of the BMJ Open Quality template for quality improvement project report. The original template can be accessed here: https://bmjopenquality.bmj.com/pages/authors/#editorial_policy

Your manuscript should include:

1. Abstract (up to 300 words)
2. Main text (up to 4000 words; excluding abstracts, tables and figures)
3. Maximum of 5 tables or figures.
4. Please use Font Arial, Size 12, double spacing.

| Subheading | Description |
|---|---|
| Title | Indicate that the article concerns an initiative to improve healthcare. |
| Abstract | This is a summary of your work and is the most important section to attract a reader's attention. Please ensure you include:<br><br>a) A brief background to the problem,<br>b) The method for your quality improvement project,<br>c) The overall results and<br>d) The conclusion<br><br>Keep it succinct and factual. Please include 3 – 5 appropriate keywords for your manuscript. |
| Problem | Summarise your problem and the focus of your project. Give some details about your local context including;<br><br>a) The type of organisation you work in,<br>b) The size of your organisation,<br>c) Details about the staff members who work there and<br>d) Perhaps a little bit about your local patient population.<br><br>Include here the SMART aim of your project (for example; the aim was to reduce medication errors from 15% to 5% across six elderly care wards in three months). |
| Background | This section gives the reader background information about the problem and provides up-to-date, research and knowledge from the literature.<br><br>Summarize the literature you have found on the background to your problem here.<br><br>a) What existing evidence is there that this problem exists?<br>b) What existing evidence is there on the factors contributing to the problem?<br>c) What evidence is there that other people have tried to solve this problem in the past?<br>d) Is there any evidence for what works and what doesn't to solve your problem? |

| | |
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| Measurement | Describe which measures you selected for studying processes and the outcomes of the intervention(s), including:<br><br>a) Rationale for choosing them,<br>b) Their operational definitions,<br>c) Inclusion and exclusion criteria,<br>d) The standard and how you determine it<br><br>Describe how you planned to collect this data throughout your project and how frequently.<br><br>Include here the results of your baseline measurement (verification study). |
| Initial assessment of the problem | Describe what processes are involved in your problem including the critical that will contribute to the achievement of your final goal.<br><br>Describe on the perceived factors that could contribute to the problem and how you quantify them.<br><br>Include here the results of the study that you conducted to identify the contributing factors to the problem. |
| Strategy | In this section you should explain your strategy for improvement to the reader and discuss how you implemented your improvement cycles. In most cases you will have tried a number of progressive improvement cycles, some of which will not have been successful. It is important that you also share these to help others avoid similar difficulties. Remember that data should be collected continuously throughout your project.<br><br>This is a difficult section to document and will contain a lot of information. For each PDSA cycle you should describe your aim, your change hypothesis and strategy for change.<br><br>a) Describe how you implemented the change and the data you collected.<br>b) Describe your key learning from each cycle of change, and discuss how this learning impacted on your change process.<br>c) How well did your predictions of what change was needed match your outcomes?<br>d) What worked more effectively than anticipated and what had less effect than predicted? |
| Results | Provide a summary of what your results using appropriate chart or diagram.<br><br>a) Describe the variation in your data.<br>b) Were the interventions you made responsible for any improvements?<br>c) Describe how contextual elements interacted with the intervention(s) and affected your results.<br>d) Compare your results to your baseline measurement.<br><br>Comment on how you assessed whether the data was complete and accurate-was there any missing data?<br><br>Please comment on whether there were any unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). |

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| Lessons and Limitations | In this section, discuss the lessons you learnt from the project and its limitations. Comment on the strengths of the project.<br><br>Describe any problems you faced and how you navigated these.<br><br>If you were to undertake this project again, what would you do differently?<br><br>Reflect on your project's limitations.<br><br>For example, did you realise as the project was implemented that your results would be affected by unforeseen factors such as a small sample size or the turnaround of patients or staff?<br><br>Comment on the limits of generalize ability.<br><br>Describe whether chance, bias, or confounding have affected your results and whether there was any imprecision in the design or analysis of the project.<br><br>Are more data points required?<br><br>Were efforts made to minimize/adjust for any limitations?<br><br>Although we accept publications using different improvement approaches, we would expect you to have modified your intervention as it was implemented and undergone a process of continuous improvement, measurement and learning. If your project does not fit with this approach then we would like to see reflections and learning here about how you could have incorporated continuous improvement and measurement approaches in your project. |
| Conclusion and the next steps | You should reflect on your background research, noting what is already known on this topic and what your project adds.<br><br>You should refer back to your aims statement – did your project achieve its aims? Did you adjust your aims as you went along? Was it a useful project?<br><br>Were your measures appropriate and did you use balancing measures?<br><br>Think about what your senior sponsor would like to see as an output of your work and what can help others to make the case for undertaking a similar piece of work – or for doing something differently if your project was not successful.<br><br>Please describe your cost analysis here, were there any financial savings that your project made? Being able to demonstrate that your intervention delivered savings really helps to add value.<br><br>Give an assessment of whether you think your project is sustainable – do you have enough data? What have you done to try to ensure that your work continues? Comment on how you would spread your project and whether it could be replicated elsewhere. Discuss what your next steps will be and whether further study in the field is required.<br><br>The point of the conclusion is not to rewrite the whole project, but to give an overview of how the whole project was conducted, what it achieved, and some personal reflections. |
| References | In this section you should record any references to published material that you refer to elsewhere in your project. This is particularly likely to include material from background reading or from your conclusions.<br><br>Use the Vancouver style for referencing. |

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